Implementing maintenance cognitive simulation therapy (CST) in practice: a randomised controlled trial (RCT) of training and monitoring studies

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Declaration

I, Amy Streater, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

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Abstract

Background: Cognitive Stimulation Therapy (CST) is a group psychosocial approach that has demonstrated benefits in cognition and quality of life for people with dementia. It is useful to determine if these benefits can be replicated in practice. Further research is also required to determine if outreach support is beneficial for staff members to implement the CST and maintenance CST programmes.

Aim: To develop and evaluate the implementation of CST and maintenance CST, with the addition of outreach support determined by number of attendees to the programme. In addition to examining the impact of CST in practice on cognition and quality of life for the person with dementia.

Methods: After preparation of the training materials a randomised controlled trial evaluated the impact of outreach support on the implementation of CST in practice. All participants received the CST manuals and DVD. A proportion of the participants were familiar with CST and the remainder were new to CST and received the full training package. Focus groups examined the views of staff on the maintenance CST programme and outreach support. An additional study examined CST in practice using basic outcome measures with people with dementia.

Results: Significantly more maintenance CST groups were run in the group receiving outreach support compared to the control group. Additionally, staff members with prior experience of CST were more likely to run both CST programmes. The observational study demonstrated improvements in cognition for people with dementia in receipt of CST.

Conclusion: Participants are more likely to run the programme if they have previous experience of CST and are in receipt of the outreach support for the CST and maintenance CST programme. Cognition can increase and quality of life can remain stable for people with mild to moderate dementia receiving CST as part of their usual care.

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Abbreviations

AChEI – Acetylcholinesterase inhibitor

AD – Alzheimer Disease

ADQ – Approaches to Dementia Questionnaire

AE – Adverse event

ANCOVA – Analysis of covariance

ASt – Amy Streater

ASp – Aimee Spector

BARCQ – Barriers to Change Questionnaire

BL – Baseline

BPS - Biopsychosocial

CDR – Clinical Dementia Rating scale

CMHTs – Community Mental Health Teams

CST – Cognitive Stimulation Therapy

DeNDRoN - Dementia and Neurodegenerative Diseases Research Network

DKQ – Dementia Knowledge Questionnaire

DMEC – Data Monitoring and Ethics Committee

DoH – Department of Health

DSM - Diagnostic and Statistical Manual of Mental Disorders

EA – Elisa Aguirre

FG – Focus group

FU – Follow up

FU1 – Follow up 1

FU2 – Follow up 2

GP – General Practitioner

HD – Helen Donovan

ISRCTN – International Standard Randomised Controlled Trial Number

ITT – Intention to Treat

JH – Juanita Hoe

JW – Jennifer Wenborn

LTSI – Learning Transfer System Inventory

MMSE – Mini mental state examination

MRC – Medical Research Council

MSQ – Minnesota Satisfaction Questionnaire

MO –Martin Orrell

MONOU – Monitoring and outreach

MREC – Medical Research Ethics Council

n – Number

NAO - National Audit Office

NICE – National Institute of Clinical Excellence

NIHR – National Institute for Health Research

NELFT – North East London Foundation Trust

NHS – National Health Service

NICE – National Institute of Clinical Excellence

NISW – National Institute of Social Workers Noticeable Problems Checklist

NSF – National Service Framework

NVQ – National Vocational Qualification

NWORTH – North Wales Organisation for Randomised Trials in Health (& social care)

p – Level of significance

PI – Principal Investigator

PWD – Person with dementia

QCS - Quality Compliance Systems

QoL – Quality of Life

QOL-AD – Quality of Life – Alzheimer's Disease

RA – Research Assistant

RCT – Randomised Controlled Trial

REC – Research Ethics Committee

RO – Reality Orientation

RT – reminiscence Therapy

R&D – Research & Development

SAE – Serious adverse event

SC – Staff caregiver

SCIDS – Sense of competence in dementia care staff

SD – standard deviation

SHIELD – Support at Home - Interventions to Enhance Life in Dementia

SPSS – Statistical Package for the Social Sciences

SSIF – Site Specific Identification Form

STANDOUT – Staff training and outreach

TAU – Treatment as usual

UCL – University College London

UK – United Kingdom

UKCRN – United Kingdom Clinical Trials Collaboration

VaD – Vascular Dementia

Ethical approval and Trial registration

Ethical approval

East London Research Ethics Committee (REC) 3 first approved the study on the 14th June 2011 (Appendix 1.1), REC reference 11/LO/0059. The original approval letter missing the deletion of a consent form that the REC considered irrelevant at the time of submission, so the approval was re-issued on the 12th July 2011 (Appendix 1.2).

Trial registration

The recruitment differed across the study and because of this was split into three, the staff training and outreach (STANDOUT) trial the monitoring and outreach (MONOU) trial and the observational study. The STANDOUT and MONOU trials were registered with North East London Foundation Trust (NELFT) (Appendix 1.3), Northampton Healthcare NHS Trust (Appendix 1.4), Tees, Esk & Wear Valleys NHS Foundation Trust (Appendix 1.5), Worcestershire Health & Care NHS Trust (via email), Nottinghamshire Healthcare NHS Trust (Appendix 1.6), North Staffordshire NHS Trust (Appendix 1.7), and Kent & Medway NHS Trust (Appendix 1.8).

The observational study was registered with North East London Foundation Trust (Appendix 1.3), Nottinghamshire Healthcare NHS Trust (Appendix 1.6), North Staffordshire Combined Healthcare NHS Trust (Appendix 1.7), Kent & Medway NHS Trust (Appendix 1.8), and South Staffordshire & Shropshire Healthcare NHSFT (Appendix 1.9).

The randomised controlled trial was registered with the International Standard Randomised Controlled Trial (ISRCTN) register and assigned the trial identification number: ISRCTN28793457.

Chapter 1: Introduction

1.1 Dementia

1.1.1 Ageing population & dementia

Government projections report that persons aged 65 and over are the fastest growing age sub-group and will account for 23 per cent of the population by 2035 (Office for National Statistics, 2012). Diagnostic rates are anticipated to double within the next 30 years (National Audit Office, 2010) and with an ageing population the number of people with dementia is expected to rise (Alzheimer's Society, 2014).

The World Alzheimer Report (2013) estimated the figure for people living with dementia worldwide in 2013 to be 44.35 million, with this figure estimated to increase to 135.46 million by 2050. Within the United Kingdom (UK) there are approximately 850,000 people living with dementia (Dementia UK, 2014) and the forecast for dementia expects to see this figure increase to over one million by 2025 and over two million by 2051 (Dementia UK, 2014). This overall increase in dementia is considered an 'epidemic' that needs to be acted upon straight away (World Alzheimer Report, 2009).

1.1.2 Definition of dementia

Dementia is a clinical syndrome that is associated with 'a gradual loss of mental and at a later stage physical functioning, that leads to disability and premature death' (National Institute of Clinical Excellence [NICE]-Social Care Institute for Excellence [SCIE], 2006, P.43). The recent Diagnostic and Statistical Manual of Mental Disorders-5 (DSM; American Psychiatric Association, 2013) use the terms 'mild and major neurocognitive disorders' instead of the term 'dementia', however one particularly useful guide for the criteria and definition for dementia is the DSM-IV (American Psychiatric Association, 1994). The DSM-IV criteria

requires for the memory deficit to be measured objectively on cognitive tests and in addition to this the person should have at least one of the following deficits; aphasia, agnosia, apraxia, or impairment in executive functioning. These cannot be accounted for by another neurological disease that impacts on the person's day-to-day living, and in turn affect their cognitive and social functioning (American Psychiatric Association, 1994). Aphasia is a language impairment that hinders the naming of objects, and later on in the progression of the disease in understanding language and speech. This can make interaction with others difficult, as people with aphasia are able to recognise objects and people but struggle in their ability to name them. Agnosia is an inability to recognise familiar objects and people, so the person with dementia can name them but can have difficulty in recognising them. Apraxia is the loss of starting or completing motor activities such as actions and movements that previously the person would be familiar with. An example of this is person with dementia is no longer able to independently dress or feed themself. Lastly, impairment in executive functioning can result in difficulties in planning, starting or completing complex tasks, or thinking in an abstract manner. An example of impairment in executive functioning is in the planning, sequencing, and cooking of a meal (First & Tasman 2011).

1.1.3 Types and prevalence of dementia

'Dementia' as an umbrella term includes many different types including Alzheimer's disease (AD), Vascular Dementia (VaD), Frontotemporal dementia and Dementia with Lewy-bodies, amongst others. In the UK the most common type of dementia is AD accounting for 62% of all cases. VaD (including VaD with Alzheimer's disease) totals approximately 27%, Dementia with Lewy bodies accounts for 4% of cases, Frontotemporal dementia makes up 2%, Parkinson's dementia 2% of cases, and 3% other (Dementia UK, 2014).

AD can be characterised through chemical and structural changes within the brain leading to the death of brain cells (Knapp et al., 2007), and common symptoms including confusion, short-term memory loss, behavioural disturbances, and difficulty in everyday functioning. As AD develops these symptoms are likely to worsen in severity due to the increased neuropathology (Förstl & Kurz 1999). However, AD is typically split into three stages; mild, moderate, and severe. In the mild stages of AD a person will generally demonstrate impairment in learning and short-term memory, in the moderate stages reasoning, planning and organisation will become impaired, and in the severe stages all cognitive functions will become severely impaired (Förstl & Kurz, 1999).

VaD is considered to be more staged in its decline occurring as a result of a lack of oxygen getting to the brain (e.g. as a direct result from a stroke). The difficulties encountered by a person with VaD, or VaD with Alzheimer's disease, are similar to those associated with AD, although VaD is typified by difficulties in the person's communication and increased levels of confusion (Knapp et al., 2007). However, the exact nature of the difficulties encountered is dependent on the location of the damaged area in the brain (O'Brien et al., 2003). Protein deposits inside nerve cells interrupting the normal functioning of the brain, affecting memory, concentration, and language skills, cause dementia with Lewy bodies. The clinical characteristics of dementia with Lewy bodies are similar to Parkinson's disease, such as slower movement. In Fronto-temporal dementia the front of the brain is affected which can impact on the person's behaviour and is commonly diagnosed in people under 65 years of age (Ratnavalli et al., 2002).

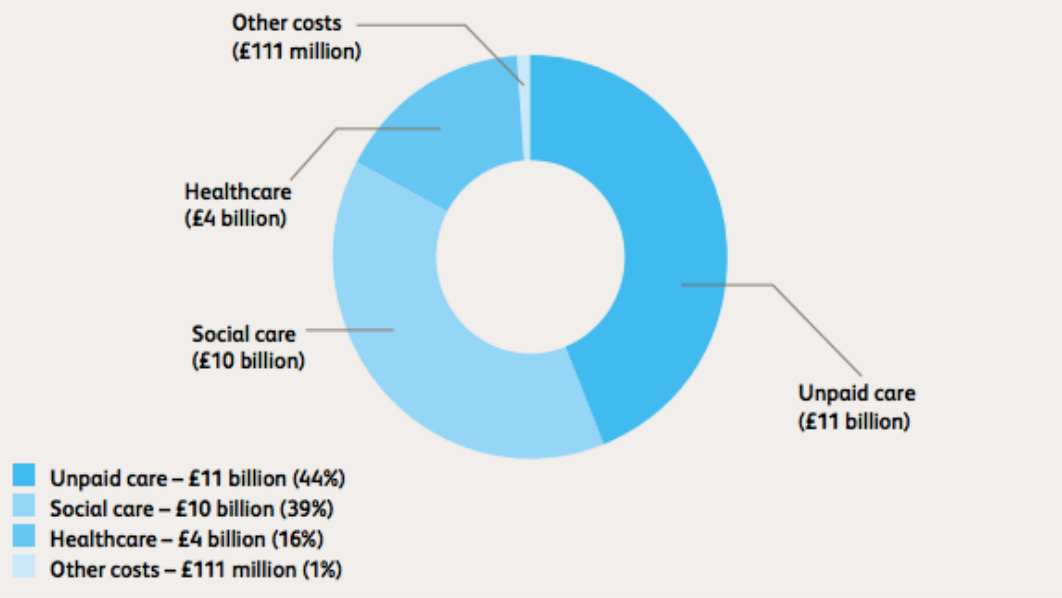
1.1.4 Projections of cost with an ageing population

The population as a whole is expected to live longer and after receiving a diagnosis it is expected that the person will live for a further 7-10 years (van der Flier & Scheltens, 2005), although a more modest estimate is 4.5

years (Xie et al., 2008). It has been reported that by delaying the onset of dementia by five years could cut the level of prevalence in half (NICE, 2006) and this could significantly reduce the global burden of dementia (Brookmeyer et al., 2007). One approach is increased cognitive activity in later life that has been associated with a decreased incidence of dementia (Prince, Albanese, Guerchet, & Prina., 2014). Arguably delaying the onset of dementia is difficult as the neuropathological changes can occur years, potentially decades before becoming apparent enough to lead to a diagnosis (Elias et al., 2000; van der Flier & Scheltens, 2005).

Dementia is a major public health problem currently costing the NHS, local authorities and the families of people with dementia £26.3 billion a year (Dementia UK, 2014). The Dementia UK update (2014) attributed the breakdown of cost to the following areas; healthcare costs, social care, unpaid care and other areas (Figure 1.1).

Figure 1.1: Breakdown of the costs associated with dementia.



The cost was determined by averaging the annual cost of care across residential care and living in the community, so the majority of cost was attributed to unpaid care at £11 billion (44%), followed by social care at

£10 billion (39%), healthcare at £4 billion (16%) and other costs at £111 million (1%). When looking at direct medical costs for hospitalisation and institutionalisation, there is a fourfold increase when the level of impairment shifts from mild to moderate dementia (Souêtre, Thwaites & Yeardley, 1999) and is to be expected due to the increased level of dependence (Chenoweth et al., 2009). Increasing costs of care are associated with the increase in incidence of dementia, and currently there is no cure (NICE, 2006).

1.1.5 Provision of care in care settings

For people with dementia living in the community day services have shown to reduce social isolation, improve mood and wellbeing (Curran, 1995). However, once a person enters into a day service they are likely to continue until they enter full time care. A meta-analysis identified the predominant predictors of admission included; dependence in activities of daily living, cognitive impairment, increased use of community based services (Gaugler et al., 2007), and lack of family involvement or when caregiver stress was high (Brodaty et al., 1993). A BUPA census in the UK identified that more than 50% of residents had dementia when entering the care system (Bowman, Whistler & Ellerby, 2004) and previous literature identified higher levels of cognitive impairment in care settings related to unmet need of residents living in care facilities (Hancock, Woods, Challis & Orrell, 2006) and was a major predictor of lower quality of care (Bravo, De Wals, Dubois, & Charpentier., 1999).

Quality of care and the services offered to people with dementia is a longstanding issue in care homes (Prince, Prina, & Guerchet, 2013) and has been associated with low staffing levels (Chapman & Law, 2009). A lack of staff training, in both understanding dementia and offering support in dementia is well documented (Fahey-McCarthy, McCarron, Connaire, & McCallion., 2009; Chapman & Law, 2009) and a common concern. However, quality of care is difficult to describe and measure, and Murphy

and colleagues (2006) highlighted the difference between quality of life (QoL) and quality of care, as focused on by policymakers. Several studies have also questioned the extent to which quality of care can be defined by the individuals' rating of wellbeing, or QoL (Ballard et al., 2001; Fossey, Lee & Ballard, 2002; Hunt, 1997) as QoL or wellbeing may be related to other factors aside from quality of care. A person with dementia has the capability to rate their own QoL (Alzheimer's Society, 2010), and it has been argued that higher QoL should be the focus for people in long-term care (Prince, Prina & Guerchet, 2013).

1.1.6 Provision of well-defined care

There has been a strong argument for well-trained staff to meet the complex needs of individuals with dementia (All-Party Parliamentary Group on Dementia, 2009; Care Quality Commission, 2013). It has been suggested that giving care staff therapeutic tools will: give them a greater interest in their work, be less institutionalised, provide greater job satisfaction, and potentially provides a lower staff turnover (Grant, Kane, Potthoff, & Ryden., 1996). Staff training has been identified as crucial in the development of good standards of care when working with people with dementia (Innes, MacPherson & McCabe, 2000).

A difficulty in understanding the role of the formal caregiver when working with people with dementia is what defines care. One definition is 'emotional support, help with decision-making, intimate care, responding to behaviour and personality changes, and coping with the risks, in addition to other health problems' (Chapman & Law, 2009). However, this does not account for the social aspects of care. When considering the delivery of social aspects of care within a variety of care settings, staffing levels, level of education and training, physical environment and access to private and public facilities should not be overlooked (Murphy et al., 2006). There is also the distinction between training in understanding

dementia and associated behavioural issues, and training in the delivery of social interactions and activities within care settings.

External stressors to the individual delivering care are well recognised, with stresses of dealing with a person with dementia, low staffing levels, pressure for quick turnaround, and a stress inducing physical environment, all contributing to perceived barriers (Chapman & Law, 2009). Other factors perceived as barriers to quality of care are; job satisfaction (Robertson et al., 1995), and a lack of time to provide individualised care (Brooker, Woolley, & Lee, 2007; Beer et al., 2009). The aforementioned factors conflict with the previously stated definition of what defines care and can impact on the persons ability to provide the care for people with dementia. Jenkins and Allen (1998) found staff that interacted more with residents had a higher sense of personal accomplishment, whereas those involved in decision-making had fewer interactions and a lesser sense of personal accomplishment. Other studies have shown that reported higher levels of anxiety by staff members impact on their ability to manage challenging behaviour (Moniz-Cook, Woods & Gardiner, 2000), and that staff burnout results in a negative impact on quality of care (Macpherson, Eastley, Richards & Mian.,1994; Mozley et al., 2004). Likewise, Todd and Watts (2005) reported that optimism and sympathy was linked to a lower level of burnout and a greater willingness to help the person with dementia.

There appear to be two main approaches to staff training. The first approach emphasises skill development and behaviour change, whilst the second approach focuses on attitude change, enhancing empathy with the person with dementia and a person-centred approach, with the implicit assumption that changes in these aspects will lead to changes in the delivery of care. Skill development and behaviour change was evaluated in a programme by Burgio and colleagues (2002) that involved staff receiving immediate feedback on performance during training,

followed by a management and reward system for staff that reinforced the maintenance of the skills learned. Results showed significant reductions in the use of ineffective strategies from staff and increased positive statements to residents post intervention.

The second approach reported by Lintern, Woods and Phair. (2000) of attitude based training, focussed on staff receiving two days of training in person centred care. In this study, changes in the expressed attitudes of staff in care practice were identified on the Approaches to Dementia Questionnaire (Lintern & Woods, 1996). There were a number of improvements in observed quality of care, including increased interaction and the opportunity for engagement in activities between staff and residents.

Zimmerman and colleagues (2005) found that attitudes to recognising personhood were related to job satisfaction, in particular enjoyment of contact with residents. Staff who perceived themselves to be better trained in dementia care reported more person centred attitudes and more job satisfaction. A link has also been made between higher levels of hope in staff members and better QoL for the person with dementia (Zimmerman et al., 2005; Spector & Orrell, 2006). If increased training can affect staff behaviour, it may impact on quality of care and service delivery. Staff attitudes and behaviour towards residents can become more positive with appropriate training and development interventions, and residents can benefit from these changes. Despite this, training alone in the absence of appropriate support from the culture, ethos and management in the home is not sufficient to improve QoL for residents or, in more general terms, change care practice (Lintern, Woods & Phair, 2000).

In dementia care the focus tends to be on outcomes in people with dementia as opposed to evaluation of the delivery of interventions, staff

behaviour and attitudes. However, when the effects on staff have previously been evaluated, training programmes have generally shown an insufficient change in behaviour and practice. Arguably, it is necessary to monitor and reinforce appropriate practice on an ongoing long-term basis to maintain staff performance (Burgio & Burgio, 1990; Kuske et al., 2007). Combining both pharmacological and nonpharmacological interventions are considered the most efficacious, particularly in treating behavioural and psychological symptoms of dementia (BPSD), although the latter should be used first in treating these (Kolanowski, Fick, & Frazer., 2010). When considering this line of treatment in care homes, as well as understanding the residents life history it has been identified that cognitive stimulation and exercise can improve mental health outcomes for people with dementia and help in managing behaviour (Kolanowski, Fick, & Frazer., 2010; Vernooij-Dassen et al., 2010). However, research studies demonstrated that staff members' are solely responsible in the initiation, direction and maintenance of activities and people with dementia are reliant on staff to access these (Lawrence, Fossey, Moniz-Cook, & Murray., 2012).

In an effort to understand nursing home staffs' decision making process when choosing interventions to treat BPSD focus groups were undertaken (Kolanowski, Fick, & Frazer., 2010). The authors concluded the use of nonpharmacological interventions requires the right education, staff member, and timing to be successful. Difficulties to implementing interventions include lower staff to resident ratio, and higher and more complex needs of the person with dementia, and a lack of understanding by the staff member in the effectiveness of nonpharmacological interventions (Kolanowski, Fick, Fraser & Penrod., 2010). In a review of studies looking at staff training in care homes and the effect on BPSD, it was found the majority of included studies demonstrated positive outcomes in BPSD for the person with dementia (Spector, Orrell, & Goyder., 2013). In addition to this, for the majority of studies, at least one

positive secondary outcome was also reported for the staff member following on from the training. Positive outcomes for staff included improvements in ability to manage behaviour, improved self-efficacy and staff attitudes, reduction in stress levels, and proxy reported improvements in staff behaviour. A recent European consensus on outcome measures for psychosocial intervention research in dementia care reported the measurement of staff factors is difficult, due to high staff turnover and a lack of focus on quality of care indicators (Moniz-Cook et al., 2008). It was identified that the psychometric properties of the study-specific measures lack the evaluation of the psychometric properties and make the comparison across studies problematic. In addition, there needs to be a focus on the development of a European perspective on job satisfaction outcomes. In summary, the evaluation of delivery of care in dementia by healthcare professionals would benefit from the standardisation of staff measures.

1.1.7 Implementation into practice

The failure to translate research findings into everyday practice is well documented (Grimshaw & Eccles, 2004; Grol et al., 2007). This includes widespread implementation, with a lack of information in regards to consideration of acceptability and effectiveness of interventions (Lawrence, Fossey, Moniz-Cook, & Murray., 2012). A difficulty arises when considering the shift between individual responsibility and external factors that may impact on the successful implementation of an intervention (Grol et al., 2007). Individual difficulties have been attributed to lack of knowledge, negative attitudes, and an underdeveloped skill set (Grimshaw & Eccles, 2004). External factors include; structural barriers, organisational barriers, inappropriate skill mix, lack of resources, peer group barriers, and professional-patient interaction barriers (Grimshaw & Eccles, 2004), as well as economic, administrative, and organisational factors (Grol et al., 2007).

There is also debate as to what works when considering implementation in practice, with educational materials, audit, feedback and reminders having demonstrated general effectiveness (Grimshaw & Eccles, 2004). In contrast, Grol and Grimshaw (2003) identified reminders, multifaceted interventions (two or more combined interventions), and interactive educational meetings as the most effective interventions. Audit and feedback, influential leaders, local consensus and patient mediated interventions were found to be of variable effectiveness, and educational materials and didactic educational meetings were shown to have little or no effect in promoting behavioural change among practitioners. So, the evidence as to the most effective teaching manner to support behavioural change remains unclear.

Five steps previously identified as necessary to change behaviour were; orientation, insight, acceptance, change, and maintenance of change (Grol, 1992). The first step, orientation, was recognised as the person being informed of the necessary guidelines, the second step, insight, placed emphasis on understanding the guidelines. The third step, acceptance, included the person having a positive attitude and with this accepting the guidelines followed by the fourth step of change, implementation in practice. The final step was to maintain the change, and recognise the associated positive outcomes. This model was detailed further with each step divided into two subsections to create a total of 10 steps to bring about behaviour change (Grol & Wensing, 2004). Both models by Grol. (1992), and Grol and Wensing. (2004), relate to the expectations and awareness of the individual, that in turn have implications for the uptake of interventions and implementation in practice.

Grol, Wensing and Eccles (2005) created a model as an implementation plan for use in healthcare. The authors identified the following issues; the complexity of the working environment, requirement for all professionals

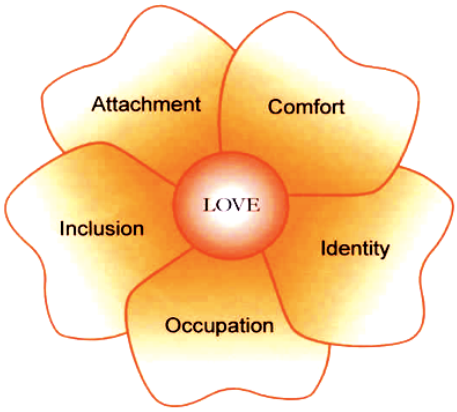
to be committed to the change, focus on the specific intervention to be implemented (particular characteristics associated with the intervention), sequential approach to problem solving, choice of measures relevant to the problem, monitoring of progress, and incorporation into an established target setting. Arguably, although a comprehensive model, all these factors would be difficult to control, and measure in practice in a pragmatic trial.

Consideration of both the individual and external factors seems to be the most appropriate course of action when attempting to understand the difficulties in integrating research into practice.

1.2 Role of cognition based psychosocial therapies in dementia care

Dementia was traditionally viewed in relation to a medical model. This model views dementia as a disease caused by organic problems with a linear trajectory, and predominantly treated in a medical capacity. Although this is still relied upon today, there has been a shift towards a social model of dementia. This model considers how the way a person is treated can impact on how dementia and associated symptoms present. The medical and social models were combined to create a dialectical model of dementia and considering both the neurological impairment and psychological factors to allow for a more personal and optimistic stance to caregiving (Kitwood, 1990). Kitwood (1997) explained the experience of living with dementia as five factors: D = P + B + H + NI + SP, where D = dementia, P = personality, B = biography, H = health, NI = neurological impairment and SP = social psychology. To varying degrees all five factors impact on the person with dementia to explain how no one person presents the same as another. An alternative model to demonstrate the five psychological needs of a people with dementia as; comfort, identity, occupation, inclusion, and attachment (Kitwood, 1997), with all these needs centred around love, and equally contributing to the QoL for the person with dementia (Figure 1.2).

Figure 1.2: The psychological needs of people with dementia



Brooker (2003) presented a similar model, V = values people with dementia, I = treat people as individuals, P = perspective of the person with dementia, and S = supportive social psychology. So, dementia is no longer perceived solely as a medical condition since there are numerous psychosocial factors. However, when personhood is negatively impacted upon it is referred to as malignant social psychology (Kitwood, 1990). Examples of this are factors such as infantilisation, treating the person with dementia like a child, outpacing, and speaking or acting in a way too fast for the person to follow.

The need for social interaction for older people with dementia is well recognised (Alzheimer's Society, 2012) and benefits include, improved QoL, promotion of social inclusion, increased mood, well-being, and self-esteem (Moyle et al., 2011; Pulsford, 1997; Spector et al., 2003). However, it is well recognised these needs can be difficult to fulfil with the person having limited access to social interaction due to living alone, having a small social group, irregular access to social activities leading to person experiencing feelings of loneliness (Cornwall & Waite, 2009).

Cognition based therapies have been developed to assist people with the cognitive deficits they may experience. The term 'cognition based therapies' has been used to describe cognitive training, cognitive

rehabilitation, and cognitive stimulation including Reality Orientation (RO) and reminiscence. However, each of these 'therapies' are worth defining further to make the distinction between each of these under the umbrella term 'cognition based therapies'.

Taulbee and Folsom (1966) developed RO as one of the first non-drug interventions for dementia. It is intended to orientate the person to the current reality, which is relevant to dementia as due to the nature of the disease the person may struggle to orientate themself to the here and now. There are two different delivery techniques of RO that can be combined. The first technique is the informal and requires the caregiver to reiterate continually the time and place to the person with dementia. The second technique is the formal where the person is delivered RO in a classroom type setting for approximately thirty minutes (Powell-Proctor & Miller, 1982). There are documented benefits of RO (Powell-Proctor & Miller, 1982) and a more recent study looking at the effectiveness of RO in the treatment of Alzheimer's disease demonstrated improvements in cognitive function compared to a control group (Carmago, Justus, & Retzlaff 2015). A Cochrane review (Spector et al., 2000) demonstrated RO to be effective in demonstrating benefits in cognition and behaviour for the person with dementia. However, the results were mainly influenced by the largest study (Breuil et al., 1994) included in the meta-analysis, and the authors identified that the majority of the studies incorporated other techniques in their approach, rather than using RO alone. Unless used in conjunction with other techniques RO has been criticised as a 'rather sterile exercise' (Powell-Proctor & Miller, 1982) and now tends to be incorporated in to other cognition based therapies, such as cognitive stimulation.

Reminiscence therapy uses discussion, in the form of group or individual basis, to focus on the past (Woods et al., 2005). Working with people with dementia plays to this strength as long-term memory is one of the last

things to deteriorate, and the focus is on their past memories. A Cochrane review of reminiscence therapy was inconclusive in its findings, as although the review demonstrated positive effects on mood and cognition for the person with dementia, due to the small sample size and variation in the delivery of the therapy, more evidence is required (Woods et al., 2005).

None of the cognition based therapies have documented adverse effects. This is important to consider when recognising the potential benefits for the person with dementia to participate in a cognitive programme demonstrating improvements in cognition, QoL, and assistance to reach set goals to maintain everyday functioning.

1.2.1 Cognitive rehabilitation

Cognitive rehabilitation is the use of therapeutic activities to build on the person's level of functionality (Cicerone et al., 2000) using an ''individualized approach to helping people with cognitive impairments in which those affected… identify personally-relevant goals and devise strategies for addressing these'' (Sinclair, Morley, & Vellas., 2012). For example, restoration utilises remaining memory by using techniques to recall information through methods such as spaced retrieval. Another technique is to develop strategies and compensatory aids to reduce the demands on the person's memory by altering the surroundings to support the person in their everyday functioning (e.g. calendar and environmental change). As opposed to placing emphasis on the level of cognitive functioning, the main focus of cognitive rehabilitation is to support the person in their day-to-day life. This in turn can impact on wellbeing, reduce excess disability, and reduce caregiver burden.

Cognitive rehabilitation can help in two main ways; by optimising the remaining memory ability to take in new information and by reducing the demands on memory by developing compensatory aids. A review of the

efficacy of cognitive rehabilitation supported its use for people with early stage dementia, and emphasised the need for flexibility in its application and a positive approach by the clinician (De Vreese et al., 2001). However, a Cochrane review (Clare et al., 2003) demonstrated the lack of Randomised Controlled Trials (RCTs) of individualised cognitive rehabilitation. The only evidence to support cognitive rehabilitation was found to be limited to single case studies and controlled group studies. A more recent Cochrane review (Bahar-Fuchs, Clare, & Woods, 2013) identified one RCT of cognitive rehabilitation considered to be a high-quality trial that demonstrated positive outcomes in self-rated competence, satisfaction in performing personal goals, memory capacity, and QoL. There is some evidence to suggest that information can be learnt and maintained over time (Anderson, Arens, Johnson, & Coppens, 2001; Camp, Bird & Cherry, 2000), that memory aids can be used to assist the person with their everyday functioning (Clare et al., 2000), and that functioning can be maintained and improved upon (Josephsson et al., 1993). However, as the Cochrane review (Bahar-Fuchs, Clare, & Woods, 2013) was only able to identify one study, no meta-analysis could be undertaken to evaluate the intervention further. Consequently, the limited evidence has to be interpreted carefully.

1.2.2 Cognitive training

Cognitive training 'involves guided practice on a set of standard tasks designed to reflect particular cognitive functions such as memory attention, or problem-solving' (Clare & Woods, 2004). The use of cognitive training works on the premise that regular practice of a task can maintain or improve functioning of a specific cognitive skill. Subsequently, the improvement in a skill set can be extrapolated to the wider context outside of the learning setting. Cognitive training can be used on an individual basis or in a group environment, with tasks ranging from paper and pencil, computer based tasks, or involving analogues of daily living. Each task can range in its level of difficulty to cater to the needs of the

individual. Outcomes are generally focused on cognitive or neuropsychological testing, with the main aim of maintaining or improving on the previous level of functioning. A Cochrane systematic review (Clare & Woods, 2003) identified six RCTs on cognitive training, and none of these studies demonstrated a significant difference between the cognitive training group and comparison group.

More recently, Olazarán and colleagues (2010) systematically reviewed the literature of the efficacy of nonpharmacological therapies (NPTs) for people with dementia. In the review, 179 RCTs were included and graded in an adapted version from the Oxford Center for Evidence-Based Medicine. Grade A demonstrated the highest level of evidence as a delay in institutionalisation, and grade B showed an improvement in cognition, activities of daily living, behaviour, mood, QoL and prevention of the use of restraints with the person with AD. A sufficient level of evidence for grade B could also be reached by demonstrating an improvement in caregiver mood, psychological wellbeing, or QoL. The authors concluded that NPTs are a cost effective approach to improve outcomes for people with AD and their carers. However, it is important to recognise that the theory was generally inadequately reported, and the quality of some of the studies was weak due to a small sample size and poorly defined method. This review recognised the necessity in the reporting of trials to describe a clear theoretical framework and a well-defined intervention to strengthen the evidence supporting research in this field. It was also noted within the review that the implementation of NPTs is generally low in cost compared to pharmacological interventions. The review was useful in clarifying important outcomes (e.g. improvements in cognition), when considering the use of cognitive training or cognitive stimulation as therapeutic interventions for people with dementia. However, the review included RCTs on cognitive training and cognitive stimulation together. Although, both of these therapies fall under the umbrella term of

'cognition based therapies' they should be considered separately, as they use different models and methods of action.

1.2.3 Cognitive stimulation

Cognitive stimulation comprises of a variety of group or individual activities and discussion, focused on information processing rather than knowledge. The aim of cognitive stimulation is to improve cognitive and social functioning for the person with dementia. However, within the literature there is an overlap between RO and cognitive stimulation. Both programmes often describe similar features, although in RO more emphasis is placed on orientating the person to the current place and time. In comparison, the focus of cognitive stimulation is on implicit information processing and it is considered that cognitive functions, such as memory, are not singular but are used in conjunction with other functions (e.g. attention and language). An example of the overlap between RO and cognitive stimulation is an RCT on a caregiver home intervention that demonstrated improvements in cognitive function and enhanced with the use of ACHeIs (Onder et al., 2005). This interaction across the two approaches and the social element of participating in a cognitive stimulation programme makes it difficult to determine what causes the benefit for the person with dementia, the cognitive component, social interaction, or both. However, previous studies have reported that when comparing a social group to a RO group, it was the RO participants that showed greater improvements in recalling information and orientation, compared to people who participated in the social group (Gerber et al., 1991; Wallis, Baldwin, & Higginbotham, 1983; Woods, 1979).

Previous research has demonstrated the efficacy of cognitive stimulation and RO for benefits in cognition and, on occasion, behaviour (Spector, Orrell, Davies & Woods, 2000; Spector et al., 2003). Although cognitive stimulation can be implemented on an individual or group basis, there is

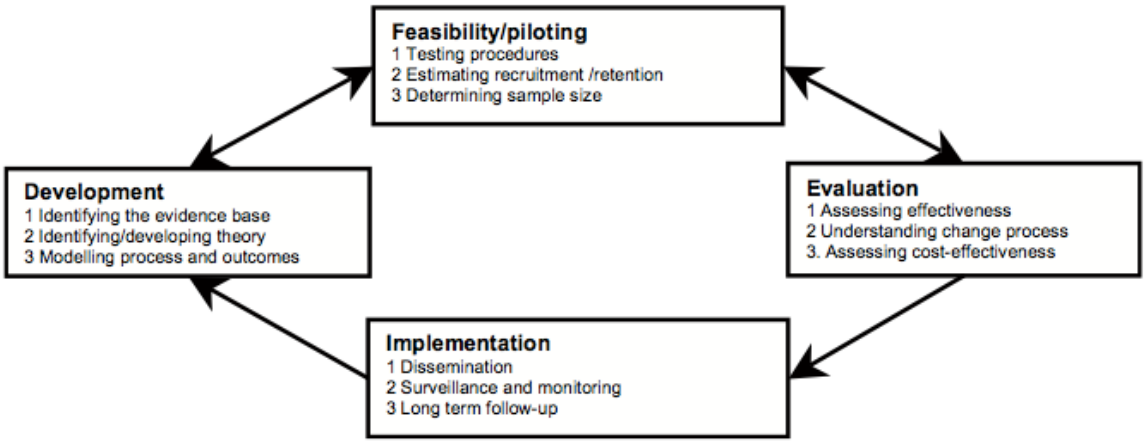
evidence to suggest that group cognitive stimulation can have positive effects for people in the mild to moderate stages of AD (Aguirre, Woods, Spector, & Orrell, 2013; Breuil et al., 1994; Spector, Orrell, Davies & Wood, 2001; Woods, Aguirre, Spector & Orrell, 2012). In addition, Spector and colleagues (2003) in a single-blind RCT of 201 people with mild to moderate dementia demonstrated improvements in cognition and QoL for those that participated in a seven week programme (14 session, twice weekly) of Cognitive Stimulation Therapy (CST). Leading on from the original programme an extended 16-week maintenance CST programme (Orrell, Spector, Thorgrimsen & Woods, 2005) was piloted and then further evaluated as a 24-week maintenance CST programme (Aguirre et al., 2010). As a large scale RCT the maintenance CST programme demonstrated benefits in QoL for the person with dementia (Orrell et al., 2014). It is now recognised that ‘‘people with mild-to-moderate dementia of all types should be given the opportunity to participate in a structured group cognitive simulation programme… with appropriate training and supervision’’. (NICE-SCIE, 2006).

1.3 Medical Research Council framework for complex interventions – best practice.

High importance in research is placed on using an evidence-based approach in the development and evaluation of an intervention to then be adopted in standard clinical practice. The Medical Research Council (MRC) devised a framework (Figure 1.3) for the development of complex interventions (2000; Craig et al., 2008) as a useful guide for policy makers and decision makers in deciding what intervention is ‘best’ evidenced. The MRC framework is divided into four phases; phase I the development of the intervention, phase II the feasibility and piloting of the intervention, phase III as the evaluation of the intervention, and phase IV the long term follow up, implementation, and dissemination of the intervention. The CST (Spector, Orrell, Davies, & Woods, 2001; Spector et al., 2003) and maintenance CST programmes (Aguirre et al., 2010; Orrell et al., 2014) have adhered to the MRC framework and as a result the programmes are

the most well documented and evidence based examples of cognitive stimulation. Due to the similarity of CST and maintenance CST both programmes will be described under the relevant section of the MRC framework, even though there was a time difference between the development of both parts to the programme.

Figure 1.3: MRC framework for complex interventions



1.3.1 Phase I: Development of the intervention

The development of CST adhered to phase I of the MRC framework and consisted of a Cochrane review examining the effectiveness of RO (Spector, Orrell, Davies & Woods, 2000). The review included six RCTs with a total of 125 participants, and concluded that there was some evidence to suggest that RO had benefits for people with dementia on both cognition and behaviour. One study that was particularly influential in the design of CST was Breuil and colleagues (1994), who carried out a single-blind multicentre RCT of 10 cognitive stimulation sessions over five weeks and demonstrated a significant improvement in cognition (p=<0.01). Due to the positive effects of RO and cognitive stimulation it was considered necessary to develop a structured group programme that could be rigorously evaluated (Spector, Orrell, Davies, & Woods, 2001).

In the development of maintenance, CST a Cochrane review was undertaken to assess the effectiveness of cognitive stimulation (Woods,

Aguirre, Spector, & Orrell, 2012; Aguirre, Woods, Spector & Orrell, 2013). This review included 15 RCTs and looked at cognitive stimulation programmes that ran for a minimum of four weeks compared to treatment as usual (TAU). One or more of the following outcomes was required to be measured; cognitive functioning, carer mood, QoL or wellbeing, everyday functioning, behaviour, neuropsychiatric symptoms, or communication. A meta-analysis was carried out to determine the combined effectiveness of cognitive stimulation and found a significant improvement in cognition, communication, self-reported wellbeing and QoL for the person with dementia.

The first version of the maintenance CST programme was developed by drawing on the evidence provided from the studies included in the Cochrane review (Woods, Aguirre, Spector, & Orrell, 2012). A Delphi consensus process was followed for the development of both CST manuals, as it is considered a suitable method for consensus building. Firstly, a consensus conference with academics, researchers, clinical staff and family carers to review the first draft resulted in a second draft of the maintenance CST manual. Secondly, focus groups were run with people with dementia, carers and staff to get their views on the activities to be included in the maintenance CST programme (Aguirre et al., 2011) and this informed the third version of the programme. Finally, a Delphi survey was carried out to develop the final draft of the maintenance CST programme. This completed the Delphi consensus process.

1.3.2 Phase II: Piloting

'Piloting' involves testing procedures related to the intervention for acceptability. This can include estimated sample size, recruitment rates, retention, and feasibility of the intervention. This stage can facilitate the evaluation phase as it has been recognised that trials can be undermined by problems relating to acceptability, compliance, delivery of the intervention, recruitment and retention, and smaller-than-expected effect

sizes (Eldridge et al., 2005). These issues can be anticipated and potentially avoided with the benefit of this stage. The importance of these factors cannot be underestimated when determining the numbers required to demonstrate a clinically significant result (Patel, Doku, & Tennakoon, 2003) and how this can impact on the internal and external validity of the study (Gul & Ali, 2010). The piloting stage can help to foresee any issues that might arise if the study was to be carried out on a larger scale. A program should be well designed, well prepared, and piloted before being incorporated into the normal channels to insight change and improve care (Grol, 2001).

Piloting of the CST programme (Spector, Orrell, Davies, & Woods, 2001) was carried out with 27 people with dementia across one day centre and three residential homes. The participants attended 15 sessions based around four phases: (1) The senses, (2) Remembering the past, (3) People and objects, and (4) Everyday practical issues. Measures completed with the person with dementia looked at cognition as measured by the Mini Mental State Examination (MMSE; Folstein, Folstein, & McHugh, 1975) and the Alzheimer's Disease Assessment Scale - Cognition (ADAS-Cog; Rosen, Mohs & Davis, 1984), depression as measured by the Cornell Scale for Depression in Dementia (Alexopoulos, Abrams, Young, & Shamoian, 1988) and rating of anxiety (Shankar, Walker, Frost, & Orrell, 1999) and the family carer completed the Relative's Stress Scale (Greene, Smith, Gardiner, & Timbury, 1982). The programme demonstrated positive trends in cognition (p=.0.08), anxiety (p=0.09) and reached significance in improving depression (p=0.02) for participants in the CST group. A significant improvement in carer psychological distress (p=0.04) was also observed. Due to the small sample size it was necessary to evaluate the programme in a large multicentre single-blind RCT.

A 16-week once weekly maintenance CST pilot study was carried out to determine if the benefits demonstrated in the original CST programme

could be replicated over a longer period of time (Orrell, Spector, Thorgrimsen, & Woods, 2005). The pilot study included two care homes in receipt of the CST programme and the maintenance CST programme, and the other two homes received the CST programme only, or TAU, for the duration of the study. Cognition improved for those in receipt of the CST followed by the maintenance CST programme in comparison to the other two groups (p=0.01). Despite demonstrating positive outcomes in cognition, the small sample size was a limitation. It was identified a large scale RCT was required to clarify the longer term benefits of the extended programme.

1.3.3 Phase III: Evaluation

Under the MRC framework for complex interventions, RCTs are considered the gold standard in research when assessing the effectiveness of an intervention and when considering if an intervention works (Blackwood, O'Halloran & Porter, 2010). For this reason, the framework was adhered to in the development and evaluation of CST. The CST programme was amended in accordance to the findings of the pilot study and a multicentre single-blind RCT of 201 people with dementia was carried out (Spector et al., 2003). A 14 session, seven week programme of CST was evaluated using the same measures as in the pilot (Spector, Orrell, Davies, & Woods, 2001), with the addition of a QoL measure (QOL-AD; Logsdon et al., 1999) for the person with dementia, and an economic evaluation of the programme. A total of 23 centres were recruited including day centres and residential care homes in the Greater London area. In comparison to the control group the participants in receipt of the CST programme showed significant improvements in cognition, as measured by the MMSE (p=0.04) and ADAS-Cog (p=0.01), as well as QoL (p=0.02).

In terms of the evaluation of the maintenance CST programme a large scale, multicentre, single blind, RCT of 236 people with dementia, across

nine community settings and nine care home settings was carried out (Orrell et al., 2014). All participants received the CST programme, and were then randomised to receive the maintenance CST programme or TAU. Self-rated QoL increased at the primary end point (after maintenance CST) (p=0.03), and there were improvements at three months on the proxy QoL (p=0.01), QoL (DEMQOL; Smith et al., 2005) (p=0.03), and activities of daily living (Galasko et al., 1997) (p=0.04). In addition to this the authors noted that participants in receipt of the maintenance CST programme and acetylcholinesterase inhibitors (AChEIs) significantly improved at three (p=0.03) and six month (p=0.03) follow up (FU). Overall, QoL improved for those in receipt of the maintenance CST programme, and cognition improved for those taking AChEIs whilst participating in the maintenance CST programme.

There has been criticism of RCTs, with the focus on outcomes rather than looking at the processes involved in the implementation of a programme in practice (Oakley et al., 2006). A current recommendation to overcome this is to use process evaluations to consider implementation, receipt, and environment to better understand the results.

1.3.4 Phase IV: Long term implementation

The focus of the implementation and dissemination stage is to translate study findings into routine practice or policy, with the publication of research results a crucial element of the implementation strategy. However, difficulties commonly arise when considering an intervention shifting from a research setting to everyday practice. Additional factors such as barriers and incentives need to be considered (Grol & Grimshaw, 2003), as it is well documented that research looking at effective implementation in practice is limited (Grimshaw & Eccles, 2004).

A series of outputs in peer review journals have demonstrated the extensive research undertaken in relation to the development, evaluation

and understanding of CST (Spector et al., 2003; Orrell et al., 2005; Orrell et al., 2014). There is however, a lack of focus in the research looking at the implementation of the programme in practice, any effect that this has on the delivery of the programme, and the effect on the outcome measures with the person with dementia.

Examining the use of CST after a one day CST training day, found that of all the respondents, only a third of staff went on to implement CST in their work place (Spector, Orrell, & Aguirre, 2011). The respondents were asked what they required to implement CST effectively. The respondents' answers included; 24% more staff support, 23% specialist supervision, 17% online forum, 16% training in other areas, and 15% regular supervision. Using these responses, and including the other comments, Spector and colleagues (2011) identified six main themes; support from colleagues, learning from colleagues, group facilitators training, facilitators experience running activities/groups, understanding of the groups, and work flexibility. However, a total of 152 CST training day attendees were contacted and there was a 50% response rate. Of the 76 respondents 27 had delivered CST, and 49 had not. The limitations of this study include a low response rate, preselected outreach support options, and the same identified barriers to not running the programme as the difficulties encountered when running the programme. In addition to these limitations as there was no FU of non-completers it is not possible to know if there is a difference between respondents and non-respondents in this pilot study. Yet, it is evident that there are perceived barriers in the implementation of CST, and this needs to be addressed in order to encourage the uptake of the intervention.

It is important to take an evidence-based intervention and understand its running in practice as difficulties arise when there is a lack of consideration of the barriers to implementation and the incentives necessary to encourage the uptake of evidence-based practice. There is

a need for collaboration between researchers and staff in real life settings, to enable the sharing of knowledge and inform practice. Recently emphasis had been placed on the implementation error and the lack of understanding in relation to treatment fidelity, more commonly known as a type III error (Vernooij-Dassen & Moniz Cook, 2014). A suggestion within this article is an amendment to the MRC framework to have an evaluation in the explanatory stage, followed by a pragmatic evaluation at the stage of dissemination and long term follow up (FU). In relation to CST the explanatory stage was implemented by a researcher instead of a clinician and due to the publication of the CST and maintenance CST programme the therapy is at the stage of widespread dissemination.

1.4 Recommendations

Recommendations in research are now widely available in the UK, through the National Electronic Library for Health, the National Institute for Clinical Excellence (NICE) and, internationally, the Cochrane Collaboration. However, it is now widely recognised that simple diffusion and passive dissemination of information are largely ineffective at changing practice (NHS Centre for Reviews and Dissemination, 1999). Implementation (as opposed to dissemination) strategies, on the other hand, have shown promise with a more systematic and participatory approach employed. Interventions such as face-to-face educational outreach visits (academic detailing) with individual practitioners and teams, computerised and manual reminders about new information, and interactive educational meetings, show some evidence of effectiveness (NHS Centre for Reviews and Dissemination, 1999). Evidence has suggested that multi-faceted interventions, combining two or more strategies, are more likely to result in favourable change in practice than single interventions (Wensing & Grol, 2005).

The NICE guidelines (2006) recommended a variety of evidence-based activity interventions as part of good practice, and meaningful activities

are part of the care home inspection process (Department of Health, 2003). Yet, the lack of stimulating activities, and the negative effect on the person's QoL has also been reported (Alzheimer's Society, 2007). Recent reports have highlighted a concern over the need for improvement in quantity and quality of activities provided in dementia care settings (College of Occupational Therapists, 2007; National Audit Office, 2007; Department of Health, 2001; 2003; 2009). Current guidelines state that all 'health and social care managers should ensure that all staff working with older people in the health, social care and voluntary sectors have access to dementia-care training (skills development), that is consistent with their roles and responsibilities' (NICE, 2006), and this is key in providing good quality care (Woods et al., 2006). The focus of non-pharmacological interventions to lessen the symptoms and increase QoL for the person with dementia, should be evidence based, readily available, and be of benefit to both the person with dementia and the person caring for them.

Chapter 2: Cognitive Stimulation Therapy (CST)

2.1 What is CST?

CST is a manualised intervention for people with dementia. The original CST programme (Spector, Thorgrimsen, Woods, & Orrell, 2006) is a group programme of 14 themed sessions, originally designed to be run twice weekly over a seven week period. The extended programme of maintenance CST programme (Aguirre et al., 2012) follows on from the original programme and is 24 sessions delivered once weekly. It is recommended that two facilitators run each session, and that the session lasts 45 minutes. The group consists of between 5-8 people, who should be at similar stages of mild to moderate dementia.

CST has adhered to the MRC framework for complex interventions, and research into the development and evaluation of the CST and maintenance CST programmes (Spector, Orrell, Davies, & Woods, 2001; Aguirre et al., 2010) including focus groups (Aguirre et al., 2011; Spector, Gardner & Orrell, 2011), results (Spector et al., 2003; Orrell, Spector, Thorgrimsen, & Woods, 2005; Orrell et al., 2014) and the delivery of the programme in the format of manuals (Spector, Thorgrimsen, Woods, & Orrell, 2006; Aguirre et al., 2012) has been reported consistently in academic journals. An extensive evaluation of the cost-effectiveness (Knapp et al., 2006; Amico et al., 2015), cognitive benefits for the person with dementia (Spector, Orrell & Woods, 2010), and analysis on who benefits most from the intervention has also been conducted (Aguirre et al., 2012).

2.1.1 Introduction to the session

Each session within the programme follows the same structure, apart from in the first session where the attendees decide on the group name and song. This remains unchanged for the subsequent sessions. The session starts with a 10-minute introduction including welcoming

everyone individually to the group, and giving everyone a name label, to encourage interaction amongst group members and facilitators. The RO board is used to bring the group's attention to the group name, date, time and whereabouts, and to encourage discussion about the weather. A softball activity is then used as a warm up exercise, with the option of group members naming the person they are throwing the ball to, to encourage group cohesion, and increase the person's level of functioning. The group then sing their chosen song and discuss a current topic taken from the daily newspaper.

2.1.2 Main activity

The main activity aims to mentally stimulate all group members, and should last approximately 25 minutes. Each session has a themed activity (e.g. orientation, categorizing objects, being creative). In both CST manuals (Spector, Thorgrimsen, Woods, & Orrell, 2006; Aguirre et al., 2012), a level A and level B activity are provided. Level A is a slightly more challenging activity than level B, yet both levels are interchangeable depending on the abilities and interests of the group members. The aim of each session is to focus on memory, concentration, linguistic skills, executive functioning, as well as encourage interaction amongst group members.

2.1.3 Closing the session

To close the session 10 minutes is designated to thank people for their attendance and contribution to the session, to sing the theme song again, to remind people of the time and day of the upcoming session, and finally to bid them farewell.

2.1.4 CST key principles

To assist people in facilitating the CST groups 18 key principles (Figure 2.1) were devised to offer guidance for people delivering the CST and maintenance CST programme. The key principles emphasise the value of mental stimulation, with the intention of challenging the person without

leaving them feeling deskilled. It is important to encourage new ideas, thoughts and associations rather than focussing on previously learnt, over rehearsed information. The use of the RO board allows the group to orientate themselves implicitly, and the facilitator phrases questions in a manner that is not demanding, for example, “do you think the weather is typical for summer?’’ CST was designed to elicit information implicitly as opposed to putting the person on the spot; this is avoided by focusing on opinion over fact, as opinion based discussion allow the person to voice their own views without the worry of answering incorrectly. By alleviating this pressure names or facts can sometimes be recalled at a later date without explicitly asking. Using objects and discussion for reminiscence allows the group members to feel comfortable when recalling events and knowledge. However, reminiscence is used as a tool to orientate the person to the here and now. The use of objects also acts as a prompt to aid recall and provides an opportunity to make the session multisensory for the attendees. For example, in the sound session the activity may involve matching musical instruments to sounds. Continuity and consistency is important to the CST programme and is maintained through the use of the group name and song and regularity in time and location of the sessions. The group environment and activities also stimulate language, and executive functioning. The groups are intended to be person centred, encouraging involvement, and inclusion to maximize potential, but also offering choice in a fun environment and through a range of activities. Respect is demonstrated in the application of the key principles and demonstrated between group members and facilitators, which in turn strengthens relationships.

Figure 2.1: 18 CST key principles

Key principle	
1	Mental stimulation
2	New ideas, thoughts and associations
3	Using orientation, but sensitively and implicitly
4	Opinions, rather than facts
5	Using reminiscence, and as an aid to the here-and-now
6	Providing triggers to aid recall
7	Continuity and consistency between sessions
8	Implicit (rather than explicit) learning
9	Stimulating language
10	Stimulating executive functioning
11	Person-centred
12	Respect
13	Involvement
14	Inclusion
15	Choice
16	Fun
17	Maximising potential
18	Building / strengthening relationships

2.2 Development of training materials

2.2.1 CST training manual

The CST programme is well established with a published 'Making a difference' CST manual (Spector, Thorgrimsen, Woods, & Orrell, 2006). The manual gives the reader details of the programme, list of themes, structure of the sessions, evidence base supporting the programme, key principles, useful resources, as well as frequently asked questions. Following the evaluation of the original programme, the pilot maintenance CST programme (Orrell, Spector, Thorgrimsen, & Woods, 2005), and the recommendation in the NICE guidelines (2006) a large scale RCT of maintenance CST was carried out (Aguirre et al., 2010). This resulted in the publication of the maintenance CST 'Making a difference 2' manual

(Aguirre et al., 2012) that follows the same structure as the original manual but includes the extended key principles, and details the maintenance CST programme including a staff training DVD.

2.2.2 CST staff training DVD development

Amy Streater (ASt) reviewed 346 feedback forms completed by attendees immediately after the training day. The feedback was excellent, with audio-visual equipment the only item frequently commented on as average. The production of the commercial DVD was to go alongside the 'Making a difference 2' manual. The DVD comprises of examples of all 21 themes used across sessions to, provide guidance on running sessions for facilitators, enable reflective learning, and improve on the clips used during the commercial training day.

2.2.2.1 Participants

RAs and staff facilitated the running of the group and were interchangeable across the filming days. The main facilitator was an assistant psychologist or RA had been running the CST groups as part of the maintenance CST trial (Aguirre et al., 2010). The co-facilitators were RAs or people who had experience of working with people with dementia, having received the one-day training on CST and who had assisted in previously run groups. Every participant met the inclusion criteria as stated in the main trial (section 6.10.1).

2.2.2.2 Plan of filming

Potential participants and their family caregiver were approached two weeks prior and received the information sheet and consent form to explain the purposes of filming. This timeframe also gave enough time for any questions to be raised. On the day of filming a RA went through the consent form and each participant and family caregiver then signed the consent form. However, they were made aware that they had the right to withdraw at any time, for any reason, and that it would have no adverse effect on the care they received.

2.2.2.3 Plan sessions

People with dementia who had completed the maintenance CST trial (Aguirre et al., 2010) were filmed over three days. The 21 CST and maintenance CST themes were split into batches of three of similar themes were filmed together. This allowed for sessions to be filmed in one continuous stream lasting fifteen minutes for each (e.g. associated words, word game, and team games). The introduction section of the programme was filmed with all three groups to put people at ease and this also encouraged continuity for the group name and song for each filming session.

2.2.2.4 Editing DVD footage

Editing of the footage was carried out in stages. Initially a rough edit of the footage was carried out by ASt and the cameraman, and then edited further. Once a portion of the footage had been cut ASp attended a half-day of editing to review the footage, and filmed an introduction for the DVD explaining the research background to CST and key principles. The final version of each session theme was approximately five minutes in length.

2.2.3 Training day development

Prior to this research being undertaken, the CST training day was either offered on a commercial or in house basis, and through Dementia UK. Due to the volume of training days required to be run as part of the research programme it was felt necessary that ASt be trained to deliver the training day. In total, ASt attended four training days, had approximately three years of CST experience prior to starting this study, been involved in the development of the maintenance CST manual, as well as being the lead in the development and production of the staff training DVD. Attending the training days allowed ASt to learn from one of the main pioneers of CST (ASp) and become familiar with the delivery,

content and format of the training as well as identifying common queries that were raised on the training day by attendees.

Prior to commencing the trial the training day slides were reviewed by ASt and amended according to the CST feedback forms that had been gathered on previously run training days, run by ASp, or one of the other CST trainers. The feedback form asked for the following information; what the person hoped to gain from the course, whether their expectations were met, and if not, why, how the course would change their way of working, what information they would share with colleagues, comments on trainers presentation and facilitation skills, and anything else that would improve the experience of the training session. The form also asked people to rate their level of knowledge and skill on CST before and after training, information related to the course content, trainer and trainer delivery, as well as how satisfied were they overall with the training day on a five point Likert scale (1 = very poor, 2 = poor, 3 = average, 4 = good, 5 = excellent)(Appendix 2.2). In total 346 anonymous feedback forms were reviewed and the training day slides altered according to any issues that arose in the dissatisfaction or comments box. However, the main feedback derived from the form was that an improvement was needed for the audio-visual equipment, and so the DVD was developed and published according to this feedback (section 2.2.2).

The training day consisted of information related to the models of dementia, psychosocial approaches and previous CST research, information on the CST and maintenance CST sessions, and key principles. Each attendee was provided with a handout to follow the structure of the day and to take away. The techniques used in the programme included didactic education, group workshops, training in group facilitating skills, assertiveness training, ‘role-playing’, training techniques for managing problems, basic principles of cognitive stimulation and person centred care, and use of activities for people with

dementia (Appendix 2.1). The aim of the training day was to provide the attendees with knowledge related to the development of the therapy to understand the evidence base supporting its development, the design and general running of the programme, and considerations for implementation in practice. A difficulty in the development of the training day presentation as a standardised programme, was that the same information was presented to all attendees with different levels of dementia knowledge, running activity programmes and understanding research. Although, the training could be tailored on the day to meet the requirements of all people attending it was difficult to manage training group sizes of approximately 30 attendees.

2.3 CST adherence

CST is a widely used therapy. However the question arises as to whether the CST programme is being run as intended, based on the 18 CST key principles. ASt, MO and ASp agreed it would be useful to have staff member's record attendance and adherence after each session. It also allowed ASt to identify any reoccurring difficulties people faced when attempting to run the CST or maintenance CST programme. Although, there was an adherence list completed by researchers in previously conducted CST research (Aguirre et al., 2010), it was considered too lengthy for staff members to complete in practice. So, ASt read through the 18 key principles and the descriptive text, and generated one question per principle (Figure 2.2). ASt, ASp and other researchers involved in the Support at Home Interventions to Enhance Life in Dementia (SHIELD) then revised this list. As a result of this it was decided that it was important to have a yes / no system of answering each question, with the option of additional comments. This was considered useful for the facilitator to explain why they had not adhered to a key principle. From this checklist it was possible to determine if the staff member had chosen not to adhere to, or had been unable to adhere to a key principle (e.g. 'the session structure was not followed as the group

members chose not to sing the group song'). It was important to ensure that the list was straightforward for ease of completion and quick to complete. This factored in time constraints and minimising staff burden, especially as some staff would be expected to run the group on top of their usual caregiving duties, and would be unlikely to be given extra time to complete the checklist. In total the adherence checklist comprised of 17 questions in relation to the 18 key principles.

One of the main aims of CST is to mentally stimulate the people participating in the programme. For the key principle of mental stimulation the question asked was, 'was the session pitched at the right level for all group members?' This question was considered suitable to determine if the group was mentally stimulating for all group members, as it is important to challenge the person but for them not to feel deskilled. Often people with dementia tend to recall information from the past that is over rehearsed and the focus of CST is new ideas, thoughts and associations so the question asked was 'were people encouraged to think of new ideas during the session?' Orientation is used in CST, but the emphasis is on it being carried out sensitively and implicitly. A focus of CST is to play to people's strengths and one way to do this is not to focus on fact based questions. So, to act as a reminder to the facilitators of the group it was asked 'did the discussion focus on opinion over fact?' People with dementia tend to enjoy reminiscence and this can be drawn on when running CST sessions, and tie into orientating the person to the here and now. An example of this is in the 'Using money' session discussion can focus on how much things used to cost, and how much items cost today (e.g. how much was a loaf of bread when you were younger? How much do you think a loaf of bread costs nowadays?). So, the key principle of using reminiscence, and as an aid to the here and now was addressed by asking 'were past experiences used to bring people into the here and now?' The key principle of continuity and consistency between sessions is supported by running each session at the same time and place, and in

a similar fashion by following the session plan as detailed in the manual. Creating a group name and song that are used throughout the running of the programme reinforced this, and this was addressed by asking ‘did you follow the session structure?’

The focus of CST is for people to learn, but for it not to feel like a student teacher relationship. This is emphasised through the key principle of implicit (rather than explicit) learning. An example of this is when completing the RO board asking group members ‘does this weather seem typical for summer?’ So, in this instance the person is becoming orientated to the time of year without explicitly asking them ‘what month are we in?’ This avoids the person being ‘put on the spot’ and to reiterate this the question was asked, ‘were indirect questions used during the session?’

Language has been shown to improve after CST and stimulating language is done in most sessions through activities such as categorisation. So, stimulating language is a key principle and the question was asked, ‘was everyone encouraged to participate in the session?’ This question was also considered to encompass the key principle providing triggers to aid recall, as encouraging participation involves the use of multisensory stimulation. The use of multisensory cues, such as the RO board and objects when prompting discussion within each session can help to aid recall, and providing triggers to aid recall is a key principle of CST. The planning, sequencing and organising of events can often become impaired for a person with dementia. There are several sessions that focus on these skills such as the planning and executing of how to make a cake in the being creative session as well as identifying similarities and differences in the faces / scenes session. Due to this a key principle of CST is stimulating executive functioning and this was addressed by the question ‘did anyone struggle to join in the session?’ Although, CST is a group programme it is important to remain

person centred and focus on the person not the dementia by identifying each person's strengths and limitations. So, person centred is a key principle of CST, and was addressed with, 'were the individual needs of the group members met?' It is important to show respect for the person and this can be demonstrated through not exposing any difficulties the person may have, and appreciating every person's point of view. The question was asked 'was respect shown between group members and the facilitators?'

When running the programme it is important to encourage interaction amongst the group members and value each other's contributions. It is important for the focus to be on the group members rather than the facilitators, and to manage the group when there is a dominant person. For this reason involvement is key principle for group members, and the question was asked 'did everyone equally contribute to the session?' This also incorporated sensory deprivation, such as lack of hearing aids or glasses that may have impacted on group participation. Importance should also be placed on the facilitator being able to recognise if a person is unable to participate due to needing their glasses or hearing aids or if they require a facilitator to sit next to them to prompt and encourage their participation in the group. Inclusion of group members is also important and a key principle of CST. It is important that everyone feel they can freely express themselves without free of judgement and for this reason the question asked 'was every opinion valued within the group?'

Both the CST and maintenance CST programme offer a level A and B activity dependent on the abilities of the group members. However, the programme is not prescriptive and activities can be tailored to the individual needs of the group. Having flexibility in the activities gives choice to people within the group and encourages them to take ownership of the group. So, choice is a key principle and it was asked 'were group members given the choice of activities for the session?' It is

important for group members to feel like the group is fun and if references are made to school then to change the sessions accordingly. The key principle of fun was asked in the question ‘did people seem to enjoy the session?’ It is common for people with dementia to be working at less than their optimum level, perhaps due to perhaps a lack of activity and so it is important to encourage people to be as active as possible. By the facilitator identifying the person’s level of functioning will help to ensure their approach is tailored to the individual. As a result the facilitator does not expect too little or much from group members and was answered by ‘was everyone given enough time to contribute to the session?’ Finally, it is common when running the CST programme for people to build up friendships with one another, and this should be encouraged by the facilitators. Addressing the key principle building / strengthening relationships was answered by, ‘is there a good relationship between group members?’

Figure 2.2: CST key principles and adherence checklist

Number	Adherence question	Key principle
1	Was the session pitched at the right level for all group members?	Mental stimulation
2	Were people encouraged to think of new ideas during the session?	New ideas, thoughts and associations
3	Was time spent on the date, time, weather and feelings of group members?	Using orientation, but sensitively and implicitly
4	Did the discussion focus on opinion over fact?	Opinion rather than facts
5	Were past experiences used to bring people in to the here and now?	Using reminiscence as an aid to the here and now
6	Did you follow the session structure?	Continuity and consistency between sessions
7	Were indirect questions used during the session?	Implicit (rather than explicit) learning
8	Was everyone encouraged to participate in the session?	Stimulating language & providing triggers to aid recall
9	Did anyone struggle to join in with the session?	Stimulating executive functioning
10	Were the individual needs of each group member met?	Person centred
11	Was respect shown between group members and the facilitators?	Respect
12	Did everyone equally contribute to the session?	Involvement
13	Was every opinion valued within the group?	Inclusion
14	Were group members given the choice of activities for the session?	Choice
15	Did people seem to enjoy the session?	Fun
16	Was everyone given enough time to contribute to the session?	Maximising potential
17	Is there a good relationship between group members?	Building/strengthening relationships

2.4 Adverse effects of CST

2.4.1 Risks and anticipated benefits for participants

There are no documented harmful side effects or adverse reactions from participation in the CST or maintenance CST programme. However, as part of the informed consent process prior to participation all participants were fully informed of the potential risks and benefits of the programme and research project. In general terms it has been identified that people with dementia see access to other people with dementia as a main source of support (Alzheimer's Society, 2010), and this can be encouraged in the group setting of the programme. Participants reported benefits such as feelings of enjoyment and self-worth after having participated in the CST programme (Spector, Gardner, & Orrell, 2011), as well as improvements in communication and memory during the maintenance CST programme (Chauhan and Orrell, 2012).

As part of the SHIELD research programme the project had a reporting procedure in place to ensure that an adverse event (AE) involving a participant or carer was reported to a senior clinical member of the research team to assess and report its level of seriousness (JH or RL). Serious adverse events (SAE) were then reported to the Chief Investigator (MO) and defined in the trial as an untoward occurrence experienced by a participant that:

- Resulted in death.
- Was life threatening.
- Required hospitalisation or prolongation of existing hospitalisation.
- Resulted in persistent or significant disability or incapacity.
- Was otherwise considered medically significant by the investigator.

A reporting form (Appendix 6.3) was submitted to the CI who assessed whether the SAE was related to the trial and was unexpected. In total 19 SAEs were reported to the research team. SAEs determined to be related

and unexpected were reported to Medical Research Ethics Council (MREC) and the trial Data Monitoring and Ethics Committee (DMEC).

2.4.2 Risks for staff

There are no documented AEs for staff members delivering the CST or maintenance CST programme. However on consideration staff members might experience negative feelings associated with being unable to run the programme if it is considered something required within their job role. Anecdotally, there have been reports of initial anxiety when delivering the programme although this is not completely unexpected due to the nature of group dynamics and leading a group of people that initially the person is unfamiliar with.

2.5 Discussion

CST is a comprehensive training package. The development of the adherence checklist, staff training DVD and consideration of the outreach support enabled further development of research into CST by conducting a phase IV trial looking at the implementation and dissemination of CST in the work place carried out by staff members.

Research findings cannot always be easily adopted as part of usual care, with only 29% of Community Mental Health Teams regularly offering cognitive stimulation (National Audit Office, 2007). However, this figure is likely to be out-dated as the data collection coincided with the published NICE recommendation (2006). More recently an audit of memory clinics in England identified that 66% had access to cognitive stimulation (Hodge & Hailey, 2013), so this figure has more than doubled since the published recommendation. However, this statistic does not demonstrate the actual number of people with dementia receiving CST.

Tying in to the development and evaluation of CST and the implementation of cognitive stimulation in practice it is useful to consider

the level of reporting of psychosocial interventions, specifically cognitive stimulation to be relevant to this thesis. It is also necessary to consider the level of implementation to consider the usefulness in the delivery of the intervention.

Chapter 3: Cognitive stimulation for dementia and its readiness for implementation in practice: a systematic review.

3.1 Introduction

The evidence base for cognitive stimulation is strong with recommendations stating 'that all people with mild to moderate dementia be given the opportunity to participate in a structured group cognitive stimulation programme' (NICE-SCIE, 2006). NICE guidelines are devised by an expert panel and are based on the best available and most recent evidence, identifying high priority areas for quality improvement. More recently the World Alzheimer's Reports (2011, 2014) state that cognitive stimulation should be routinely offered for people with early stage dementia and is considered to have the 'strongest evidence by far' (World Alzheimer Report, 2011). In addition to these recommendations an economic analysis was conducted to compare CST to usual activities (Knapp et al., 2006) using measurable outcomes of cognition and QoL for the person with dementia. The analysis findings demonstrated no cost difference between CST and usual activities. The authors concluded that CST was more cost effective than usual activities, based on the outcome measure benefits for the person with dementia. However, despite the aforementioned well-documented benefits for people with dementia to participate in the CST programmes and the strong evidence base to support its use in routine practice, the evidence for cognitive stimulation implementation readiness and dissemination is lacking.

The more recent shift following the MRC framework for complex interventions (2008) placed emphasis on the implementation phase of interventions to demonstrate the applicability of the intervention in real life settings. This framework is important, as it has been identified that passive dissemination of information is ineffective in altering practice

(Bero et al., 1998). Therefore, to report cognition-based therapies to a high standard research should follow the MRC framework as a guide to conduct and publish research findings. By adhering to the framework would assist in identifying the usefulness of the intervention, how it works, and provide enough detail so that the implementation phase of the framework can be explored fully. In addition to this, the implementation of interventions needs to be reported adequately to further the use of cognition based therapies in older people care settings. Previous research findings have reported methodological problems in the reporting criteria for selecting studies (Bero et al., 1998). Prior to 1991 the reported reviews scored 20% and post 1991 reviews scored 52% (Bero et al., 1998), with a lack of focus on cost effectiveness for strategies that may effect change in behaviour (Bero et al., 1998). This figure may have increased, but there is still some way to go in reporting to a high standard. More recently a framework identifying the planning, delivery, evaluation / results reporting, and long-term outcomes has been devised to highlight the evaluation and reporting elements relevant to getting research into practice (Neta et al., 2015). Similarly the RE-AIM framework (Glasgow, Vogt & Boles., 1999) comprising of reach, efficacy, adoption, implementation, and maintenance identified these five factors to establish the public health impact of an intervention. However, there is no strict guidance in the reporting of interventions and the use of these frameworks is optional in the reporting of research.

3.2 Background to systematic literature review

Woods and colleagues (2012) conducted a Cochrane review on cognitive stimulation using the definition of an ‘engagement in a range of activities and discussions (usually in a group) aimed at general enhancement of cognitive and social functioning’ (Clare & Woods, 2004). In total 15 RCT’s were identified enabling the authors to evaluate the effectiveness and impact of cognitive stimulation, specifically in relation to cognitive functioning in the person with dementia. The Cochrane review used a

meta-analysis to demonstrate a significant positive effect on cognition, QoL and wellbeing with the delivery of a cognitive stimulation programme, as well as positive outcomes of social interaction and communication as rated by the staff member. This demonstrated the beneficial effects of cognitive stimulation beyond cognition alone. However, this review did not go further in identifying the usefulness of the reporting in the included studies and how easily implemented the intervention would be in practice.

To determine the level of applicability from research findings in to a real life setting, it was necessary to identify the level of detail provided within academic material advocating the use of cognitive stimulation. The Cochrane review provided a useful starting point to research an evidence based cognitive programme and ASt was able to update the literature search. After identifying the relevant papers the newly devised Implementation Readiness (ImpRess) scale, as described in the adaption of scale section (section 3.6.1), was then applied to high quality research papers e.g. RCTs. This review builds on the findings of Woods and colleagues (2012) by examining key questions necessary for widespread implementation.

The term ‘readiness for implementation’ will be used throughout the text to; describe the level of detail provided within a research paper to assist the reader in applying what they have read (e.g. cognitive stimulation), and to detail how far it has been put in to practice. The systematic literature review aimed to provide a comprehensive account to demonstrate cognitive stimulation and its readiness for application into practice.

3.3 Aim & objectives

To design and conduct a systematic review of cognitive stimulation, and focus on readiness for implementation. In particular, with the aim to:

- Develop a scale to measure the readiness for implementation of studies reporting cognitive stimulation and other psychosocial interventions.
- Identify the level of comprehensiveness in the reporting of cognitive stimulation studies in relation to the newly devised implementation criteria.
- Grade studies in terms of the interventions readiness for implementation.
- Use the 'ImpRess' scale to identify if it is a lack of information provided in the text that encourage a lack of uptake of research findings, or if there is a high standard of reporting but that it is not being translated into practice.
- Test the applicability of the scale to other cognition based approaches (cognitive training & cognitive rehabilitation).

3.4 Methods

3.4.1 Search strategy

A systematic search for RCTs of cognitive stimulation and dementia was carried out. The studies were identified from a search of PsycINFO, Medline, EMBASE, CINAHL and SCOPUS. The search terms used for cognitive stimulation were: 'cognitive stimulation', 'reality orientation', 'memory therapy', 'memory groups', 'memory support', 'memory stimulation', 'global stimulation', 'cognitive psychostimulation' on the 23rd April 2013. The search time limits set for retrieving studies was set between January 2011 and April 2013 to provide the most up-to-date studies available. In addition to the 15 RCTs identified in the Cochrane review by Woods and colleagues (2012), two additional papers excluded in the original review (Gerber et al., 1991; Hanley, McGuire & Woods, 1981), were included for grading of implementation readiness. These papers were excluded in the Cochrane review as the data required for the meta-analysis was not available. However, as this information was

unnecessary for this review it was considered suitable to include these papers. Consequently, 17 papers were included that were identified in the original search by Woods and colleagues (2012) Cochrane review. Following on from this an updated systematic search of the literature identified 2219 papers in the initial search. After duplicates (85) were omitted there were a total of 2134 papers. After initial screening of titles, this number went down to 24 for further screening. The 24 papers were then reviewed further by abstract, and there were three remaining papers that met the inclusion criteria. In total 20 papers were included in this review.

3.4.2 Inclusion criteria

The inclusion criteria of the Woods and colleagues (2012) Cochrane review was followed in order to ensure articles returned from the new search adhered to the previously conducted literature search.

3.4.3 Included studies

RCTs that:

- Met the definition of cognitive stimulation by Clare and Woods (2004).
- Were published and written in English, and in a peer reviewed journal.
- Had a researcher, staff member or family caregiver deliver the intervention to people with dementia.
- Demonstrated significant beneficial effects on cognition and/or behaviour for the person with dementia.

3.4.4 Participants

Participants had a recognised diagnosis of dementia (Alzheimer's disease; VaD; mixed Alzheimer's and VaD; and other types of dementia) including all levels of severity of cognitive impairment measured by

standard scale (e.g. MMSE). The participants could receive the intervention in a variety of care settings.

3.4.5 Types of intervention

Participants attended cognitive stimulation sessions, as defined by Clare and Woods. (2004), for a minimum of four weeks. However, no restrictions were placed regarding the length or number of sessions made available to the person with dementia. The intervention was required to target cognitive or social functioning, offering generalised cognitive practice that could also include RO. The intervention needed to be compared to a control group of 'no treatment', 'standard treatment' or placebo activities (e.g. usual care, social group).

3.4.6 Outcomes

Outcomes looking at performance on at least one psychometrically sound test of cognitive functioning was required (including tests of memory and orientation). The following were also considered outcome measures for the person with dementia:

- Self-reported, clinically rated or carer-reported measures for mood.
- Self-reported or carer-reported QoL or well-being measures.
- Observer or carer ratings of everyday functioning (activities of daily living)
- Carer ratings of the person with dementia's behaviour.
- Clinician or carer ratings of neuropsychiatric symptoms for the person with dementia.
- Clinician or carer ratings of communication, social interaction/ engagement for the person with dementia.

3.5 Method

Data gathered included studies used in a recent Cochrane review, by Woods and colleagues (2012). The search was updated using the same

search terms as this review, and additional papers were added to the included studies, to be reviewed for readiness for implementation. Readiness for implementation of the intervention was measured using a 26-question checklist across 10 themes (motivation, theory of change, implementation context, experience, planning consultations, delivery collaborations, manager support, employee support, resources and population characteristics).

3.6 'Implementation Readiness' (ImpRess) scale

3.6.1 Development and adaption of scale

The scale was developed from a thematic checklist for the appraisal of the reporting, planning and implementation of workplace interventions (Egan, Bambra, Petticrew, & Whitehead, 2009), to appraise the quality of reporting of implementation. This checklist was applied to four systematic reviews of complex interventions used in the workplace. Focussing on 'up-stream' health determinants such as employment and transport that are difficult to evaluate, the appraisal tool reviewed; task restructuring, employee participation, compressed working week, and shift work. The original checklist was very brief with 10 questions across 10 themes including; motivation, theory of change, implementation context, experience, planning consultations, delivery collaborations, manager support, employee support, resources as well as populations characteristics. For each theme a yes or no response was required. The authors identified that the appraisal checklist assessed the reporting, but not the quality of implementation. The authors recommended a more qualitative approach to provide this information. However, the purpose of developing this appraisal checklist was to gather enough information in relation to the level of implementation readiness quantitatively so that the need for a qualitative approach would be minimised, due to the time consuming nature of this approach.

The titles for the 10 themes were lifted from the original checklist, as they were considered useful to provide the context for the intervention. However, the questions were adapted and amended to be able to be specifically applied to the MRC (2008) framework for complex interventions. This was to ensure that the scale gathered information that is currently perceived as important in increasing the implementation of interventions in practice. To determine:

- What the intervention entailed.
- Whether the intervention was implemented fully or adhered to good practice guidelines.
- Whether there were any external variables in the wider social context that would affect the implementation of the intervention.

The question themes were expanded to gather this information, as the original checklist was considered too short and vague to provide enough information to be useful when considering implementation readiness. The initial scale consisted of 40 questions that were generated by ASt and MO, and the second draft was based on further discussion with ASp. This helped to identify unnecessary questions as; not relevant in helping to identify the interventions readiness for implementation, too vague, or too similar to be able to easily differentiate from one another. Consequently, the scale was reduced to 26 questions across 10 themes (Figure 3.1).

Figure 3.1: 'ImpRess' scale

#	Theme	N	Question
1	Motivation (max score 10)	1	Does the existing evidence suggest the intervention is likely to be cost effective?
		2	Does the existing evidence suggest the intervention is likely to be effective for the primary outcome?
		3	Does the existing evidence suggest the intervention is likely to be effective for other key outcomes?
		4	Are there other benefits for the patient (qualitative)?
		5	Are there benefits for the organisation?
2	Theory of change (max score 8)	6	Are the outcomes clearly defined?
		7	Is how the intervention works clearly defined?
		8	Is the design suitable for the kind of intervention (RCT)?
		9	Is there a coherent theoretical base?
3	Implementation context (max score 4)	10	Is the intervention standardised?
		11	Can it be widely implemented in to practice (following on from research setting)?
4	Experience (max score 4)	12	Is the skills and experience of the person delivering the intervention clearly described?
		13	Is there monitoring of the delivery (attendance/adherence) of the intervention?
5	Planning consultations (max score 4)	14	Is the amount of time necessary to set up the intervention specified?
		15	Is the planning and setting up of the sessions clearly described?
6	Delivery collaborations (max score 4)	16	Does it specify the amount of time required for each session and for the duration of the programme?
		17	Are the potential and facilitator barriers to the delivery of the intervention specified?
7	Manager support (max score 2)	18	Is the level of managerial support described during the intervention/evaluation?
8	Employee support (max score 2)	19	Is the level of support required by staff members to deliver the intervention described?
9	Resources (max score 10)	20	Are the resources required to deliver the intervention specified?
		21	Is the training costs specified?
		22	Are the training materials specified?
		23	Are there manuals for the intervention?
		24	Are the materials easy to source?
10	Population characteristics (max score 4)	25	Are the population characteristics described?
		26	Does it specify who benefits most from the intervention?

Each question required a yes or no response and was then scored depending on this response. If the question was answered fully a score of two was assigned, if partially answered a score of one was given and if the answer was no, or not specified, a score of zero was given. A higher score (min 0, max 52) indicated a higher level of readiness for implementation as determined by the 'ImpRess' scale. All the papers that were included in this review were reviewed and scored by ASt. Any uncertainties regarding the scoring of a paper was then queried with MO or ASp until a consensus was reached.

Each theme was devised to appraise the level of information currently reported within the paper. These themes will be explained below in more detail to provide a comprehensive account of what was looked at within the text for the rating scale to be applied.

3.6.2 Motivation

'Motivation' to use the intervention attempted to identify cost effectiveness (Q1), the expected beneficial effects in outcomes for the person with dementia and organisation, and any qualitative information gathered on the intervention.

3.6.2.1 Cost effectiveness

Cost effectiveness as focussed on by policymakers was determined from evidence presented in the paper based on an economic analysis of the intervention, as opposed to anecdotal evidence provided by the authors.

3.6.2.2 Outcome measures

To determine if the chosen outcome measures within the study were likely to be effective it was expected that previous literature would be presented in the introduction to the paper to justify the use of the outcome measures (Q2 & 3). By identifying previous research that had used the same outcome measures to determine the effects of the

intervention highlighted a motivational aspect to the delivery of the intervention (e.g. a significant effect for the person with dementia). So, irrespective of the outcome of the measures used, if there was no justification for the use of a particular measure in question the study was not assigned a full mark.

3.6.2.3 Qualitative evidence

Qualitative evidence could be provided through the use of focus groups or individual interviews (Q4). If either of these were used a maximum score of two was given. If the authors provided anecdotal evidence, generally found in the discussion section, then a score of one was assigned. This question was relevant to ensure that there was the reporting of benefits for the person with dementia or staff member in addition to any outcome measures used.

3.6.2.4 Organisational benefit

Benefits to the organisation (Q5) were identified by recommendations and guidelines (e.g. NICE) written in the paper. If any were referenced in the study then a full score was assigned. If anecdotal evidence was provided of benefit for the staff member, centre, or organisation, then a score of one was given. An overall maximum score of 10 could be scored for motivation.

3.6.3 Theory of change

'Theory of change' identified the outcome measures, the model of how the intervention worked, design of the study, and the theoretical base (Q6 & 9).

3.6.3.1 Theoretical base and clearly defined outcomes

Outcome measures were categorised as 'Theory of change' as the purpose was to identify differences between follow up time points. Describing them in detail was necessary in order to replicate this part of the study design, by identifying what outcomes were being measured and

the tools used to measure this. For a full score on the outcome measures there needed to be a comprehensive explanation of each of the outcome measures with an explanation of the scoring. If only one of these points was answered a partial score of one was given.

3.6.1.2 How the intervention works clearly defined

Within the introduction or discussion a definition of how the intervention worked (Q7), in regards to the mechanism of change a description was required in order for a full score to be given.

3.6.2.3 Suitability of study design

The suitability was related to the design of the intervention with an RCT being accepted as the 'gold standard' for trial design under the MRC framework for complex interventions (2008). For the purposes of this review the inclusion criteria stated RCTs only (Q8), so a score of two was applied to all included studies. RCTs were chosen for this review as being the most likely to be ready for implementation and the study design written to a high standard. In regards to the theoretical base for conducting the intervention there needed to be a focus on how theory applied to the research (Q9), and justify the use of the intervention. Including these four questions showed how the intervention fitted in the research context. A total of eight out of 52 could be scored for 'Theory of change'.

3.6.4 Implementation context

3.6.4.1 Standardised intervention & implementation

'Implementation context' focused on the standardised nature of the intervention and its reproducibility in a real life setting (Q10 & 11). A full score was assigned to studies that provided a comprehensive description of the design and delivery of the intervention. When considering the reproducibility in a real life setting the study needed to incorporate details relating to the type and delivery of the intervention, resources, and type of

person required to deliver the intervention. If it was considered that a person could use the study to implement cognitive stimulation in the workplace then a full score was assigned. If these elements were not fully detailed then a partial score was given, and if these details were lacking then the study was assigned zero. This theme was important to check whether the intervention was ready to be disseminated on a larger scale, and could be followed according to the design of the intervention. A maximum of four points could be assigned to 'Implementation context'.

3.6.5 Experience

3.6.5.1 Skill set required for delivery of the programme

'Experience' as a theme identified the level of experience required by the person to deliver the intervention. If details were given in relation to level of experience required by the staff member to deliver the programme then a full score was assigned. If there was mention of the type of person delivering the intervention, but no further detail was provided, then a partial score was assigned, and if no mention was made then the study scored a zero.

3.6.5.2 Monitoring of the delivery of the programme

Monitoring was considered to include the recording and detailing of attendance and adherence to the intervention (Q13). If these elements were discussed a full score was assigned. If dropouts were described then a partial score was given as this implied that attendance had been monitored even though it was not explicitly written in the text. This information was useful in order to identify the ease of use of the intervention in different care settings (e.g. whether the person delivering the intervention needed to be qualified to a high level, so due to this might make the intervention harder to implement). A total score of four could be obtained for 'Experience'.

3.6.6 Planning consultations

3.6.6.1 Planning & time required in setting up the programme

'Planning consultations' as a theme was used to identify text describing the level of information detailed within the study in the setting up and planning of the intervention and sessions (Q14 & 15). This theme scored on the level of detail provided in regards to the amount of time required prior to the delivery of the intervention. Firstly, it was considered whether there was sufficient information in regards to the amount of time necessary to prepare the delivery of the programme and secondly whether there was enough detail in relation to the planning and setting up required. This information was useful as it could impact on whether people were able to implement the therapy since too much preparation/set up time may have stopped it going ahead in a care setting. A maximum of four could be scored for 'Planning consultations'.

3.6.7 Delivery collaborations

3.6.7.1 Delivery time and perceived barriers of the intervention

'Delivery collaborations' included time required to deliver the intervention and potential barriers to deliver the programme (Q16 & 17). This included the amount of time necessary to run the session, overall programme plan, potential or lack of barriers related to the intervention, and difficulties a person might experience when delivering the therapy. Focussing on these elements of the delivery of the intervention enabled a descriptive account in the planning and organisation that need to be considered when implementing the intervention in practice. A partial score for potential barriers was assigned if the authors highlighted any difficulties or lack of difficulties, but with minimal description. If the authors attempted to detail further the lack of, or perceived barriers a full score was assigned (maximum score four).

3.6.8 Manager support

3.6.8.1 Level of managerial support

Looking at 'Manager support' enabled the identification of the level of support required within the workplace in order to implement the therapy, and whether this had been considered or commented on (Q18). If managerial relations had been commented on and explained within the text a full score was given, if it had been mentioned briefly then a partial score was assigned, and if there was no mention of this then a score of zero was assigned. This information was useful to consider the ease of implementation of an intervention in the workplace. For 'Manager support' a maximum score of two could be assigned.

3.6.9 Employee support

3.6.9.1 Level of staff support

Looking at the reporting of level of 'Employee support' required by staff was useful when considering implementation into practice (Q19). If staff delivered the intervention, or a description had been made to the necessary or unnecessary level of support required by other staff members then a full score was assigned. If there was mention of support, or lack of, then a partial score was given, and if there was no mention the study scored a zero. The reporting of this information was important when considering the support required when implementing the intervention in the workplace, as it may impact on its level of successfulness in practice (maximum score of two).

3.6.10 Resources

3.6.10.1 Resources, training & associated costs

Training has been identified in psychosocial interventions as hard to access or not readily available (Orrell, 2012) with many interventions having no training manual or being so poorly specified that the intervention cannot be reliably replicated in practice (Orrell, 2012). So,

'Resources' as a theme identified whether the study made reference to: resources required to deliver the intervention, the cost of training (if applicable), training materials, manuals, and the sourcing of materials (Q20, 21, 22, 23 & 24). Each of these elements was broken up into its own question. If details were given then a full score was given, if mention was made to the resources then a partial score was assigned and if there was no mention within the text then the study scored zero. For instance, if examples of activities were provided with an overview of materials a partial score was assigned. To provide this information was useful as it may be a factor that hinders the implementation of the therapy. Funding the intervention may be problematic if a large amount of equipment were needed for successful implementation. A total score of 10 could be assigned for 'Resources'.

3.6.11 Population characteristics

3.6.11.1 The population the programme is for

The tenth theme was 'Population characteristics' to provide insight into whom the intervention was for and who it benefited most (Q25). For a full score to be awarded for the description of the population characteristics the following details were required: (1) type of dementia, (2) exclusion criteria, (3) level of impairment, (4) intervention setting, (5) age range, (6) gender, (7) ethnicity, and (8) country of residence. These details were considered necessary to give a comprehensive account of the intended target population. If two or fewer of these were mentioned a score of zero was assigned, if between three and five were listed a score of one was given, and if six or more were detailed a maximum score of two was assigned.

3.6.11.2 The population that benefits most

To gain a maximum score for the second question of who gained most from the intervention the study was required to highlight a particular subgroup, if any that benefited most from receiving the intervention (Q26).

This information was considered useful in practice to determine if whom, if anybody should have preference to the cognitive stimulation programme. If this was anecdotal (e.g. it appeared that a subgroup was enjoying / benefiting more) then a score of one was given, if it was not mentioned a score of zero was assigned. A maximum of four could be scored for ‘Population characteristics’.

3.7 Description of studies

For details relating to the study, type of intervention, alternative to intervention, who delivered the intervention, the level of training received and resources see Table 3.1.

Table 3.1: Cognitive stimulation studies overview

Study	Intervention	Content of therapy	Alternative activity	Who delivered intervention	Training	Resources
Akanuma et al., 2011	60 min, 1 time a week, 3 months	Group reminiscence approach (GRA) & RO.	Supportive care to control arm	4 staff members (nurse, psychologist, speech therapist & OT)	None described	Example of discussion topics provided
Baines et al., 1987	30 min, 5 times a week, 4 weeks	RO board, multisensory stimulation	Reminiscence therapy/no treatment	6 staff members trained & a research clinical psychologist	6 hours of introductory talks, videos, discussions & hand outs.	Training materials & materials for sessions described
Baldelli et al., 1993	60 min, 3 times a week, 3 months	Formal RO	No treatment (TAU)	None described	None described	None described
Baldell et al., 2002	60 min, 5 times a week, 1 month	Physical therapy augmented by RO sessions	No details	None described	None described	None described
Bottino et al., 2005	90 min, 1 times a week, 5 months	Temporal and spatial orientation, discussion of interesting themes, reminiscence activities, naming people, daily activities	ACHEIs only	None described	None described	None described
Breuil et al., 1994	60 min, 2 times a week, 5 weeks	Drawing, associated words, object naming, categorizing objects	Usual care	Two therapists, one physician & one psychologist	None described	Examples provided

Buschert et al., 2011	120 min, 1 time a week, 6 months	Multi-component cognitive group intervention - for AD group emphasis on cognitive stimulation	Pencil and paper exercises for self-study & monthly meetings	'Instructor'	None described	Examples provided
Chapman et al., 2004	90 min, 1 time a week, 8 weeks	Current events, discussion of hobbies & activities, life story work, links with daily life encouraged	ACHEIs only	Licensed speech therapist & three master's level speech-language pathology students	Education on AD, communication techniques, & instruction on how to create Life Stories Book.	Training materials & materials for sessions described
Coen et al., 2011	45 min, 2 times a week, 7 weeks	Cognitive stimulation	No treatment	Occupational Therapists & Activity co-ordinator	None described	Manual to run sessions
Ferrario et al., 1991	60 min, 5 times a week, 21 weeks	Classroom RO	No treatment	Volunteers trained by physicians & psychologist	Yes, but no details provided	None described
Gerber et al., 1991	60 min, 4 times a week, 10 weeks.	Enhanced RO	Social interaction group & control group	None described	None described	Blackboard for RO. No detail of materials for session activity
Graessel et al., 2011	120 min, 6 times a week, 12 months	Motor stimulation, practice in daily activities & cognitive stimulation	No treatment (TAU)	Two therapists (registered nurses) & one aide	None described	Manual to run sessions
Hanley et al., 1981	30 min, 4 times a week, 12 weeks	Classroom RO	No treatment	One/two staff members	Training in RO	Training materials & materials for sessions described
Maci et al., 2012	240 min, 5 times a week, 3 months	Physical & cognitive stimulation	Usual care	2 trained psychologists, PE students, & supervision by trained neurologist.	3 months of training in AD	Examples of physical activity, none for CS

Onder et al., 2005	30 min, 3 times a week, 25 weeks	Current information, topics of general interest, historical events & famous people, attention, memory & visuo-spatial	AChEIs only	Caregivers trained by physicians, psychologists & therapists.	Trained in RO	Manual & schedule to run session
Requena et al., 2006	45 min, 5 times a week, 24 months	Orientation, body awareness, family & society, reminiscing, animals, people & objects	AChEIs only. No treatment	None described	None described	TV for visual stimuli. Pictures & sounds with questions varying in level of difficulty
Spector et al., 2001	45 min, 2/3 times a week, 7 weeks	Orientation, categorizing objects, sounds, number, physical & word games, current events	No treatment	Researcher & member of staff	None described	Manual to run sessions.
Spector et al., 2003	45 min, 2 times a week, 7 weeks (14 sessions)	Orientation, categorizing objects, sounds, number, physical & word games, & current events.	No treatment	Researcher	None described	Manual to run sessions.
Wallis et al., 1983	30 min, 5 times a week, 3 months	Repetition of orientation information, charts, pictures, touching objects & materials.	Diversional occupational therapy	6 Occupational Therapists	Trained in RO by Head Occupational Therapist	RO showed in charts & pictures. Objects & materials when appropriate.
Woods et al., 1979	30 min, 5 times a week, 20 weeks	Daily personal diary, group activities, naming objects, reading RO board	Social therapy	Care staff	Discussion, demonstration, handouts, & supervision of treatment group each week.	Examples provided - Daily personal diary, spelling games, dominoes, simplified bingo

3.8 Level of reporting results

3.8.1 Motivation

'Motivation' was scored out of 10, and the included studies ranged from zero to six, with a median value of two across studies. There was a lack of information across the included papers detailing the different aspects of motivation. Only one paper included information relating to the cost effectiveness of the intervention in a formal capacity by referencing an additional paper of an economic analysis of the intervention versus treatment as usual (TAU). Two other papers mentioned costing in passing, with one intervention considered relatively inexpensive and the other considered expensive to run. All papers, excluding three, provided sufficient detail evidencing the choice of primary outcomes. In relation to evidence suggesting effectiveness for other key outcomes seven studies provided supporting evidence. Zero was assigned to the studies if the question was not applicable (e.g. no secondary outcomes defined or not adequately reported to support the use of the outcome measures assigned).

In relation to qualitative benefit for the participant only three studies provided evidence of this. This ranged from group members claiming to have positive feelings when attending the sessions and continuing to meet after their research involvement, feedback from a therapist who reported good interaction and enthusiasm amongst the participants and better knowledge of residents. Although, these benefits should not be ignored, the reports were observational and were not recorded in an official capacity. So, these observations may be open to interpretation, depending on the individual reporting these findings. Only two studies highlighted the organisational benefit as reported in the NICE recommendations (2006).

3.8.2 Theory of change

All the included studies stated the outcome measures used to assess the participants within each study. However, the description varied in length, level of detail, and scoring of the measure. Only two studies scored a maximum score for providing a detailed description of what outcomes were being measured, what they measured, and scoring. Two studies were assigned a zero for not clearly defining the outcome measures, as the measures were stated but no further detail was given. The remaining 15 studies were assigned one point for providing partial details on the outcome measures being used.

The majority of studies clearly defined how the intervention worked except for five studies that omitted this information. These explanations varied from concepts such as retrogenesis and errorless learning, to targeting psychological and social abilities, implicit memory, active engagement, and retrieval cues. The majority of studies also provided a sufficient theory base by drawing on previously conducted research in RO and cognitive stimulation to describe how the intervention was perceived to work. All of the included studies were RCTs and so were assigned a full score for a suitable study design.

3.8.3 Implementation context

All 20 studies met the criteria for providing a clear explanation of the standardised intervention. Seven of those studies went further by providing sufficient detail for the intervention to be implemented to some degree into practice, and ten studies provided enough detail for the intervention to be fully put into practice. A partial score was assigned for studies that went some way in describing the intervention but did not provide full details in order for the intervention to be lifted from the paper and applied in a care setting.

3.8.4 Experience

Over half of the included studies detailed the level of experience of the person delivering the intervention and so received a full score. However, in one study a score of one was assigned for an 'instructor', as no further information was detailed in the paper regarding the level of experience or training of that individual.

In regards to the monitoring of attendance and adherence of the intervention only two studies provided full details. A partial score of one was assigned to seven studies for providing details relating to drop outs inferring that records of attendance were kept. One other study detailed weekly meetings to ensure the intervention was delivered as designed.

3.8.5 Planning consultations

'Planning consultations' as a theme highlighted a lack of reporting within the studies. One study made reference to the small amount of time necessary to set up the intervention, whilst two studies provided details regarding the planning of the session structure. Aside from these aforementioned studies no details were provided concerning the consultation and planning necessary to deliver the intervention.

3.8.6 Delivery collaborations

All studies provided full details on the frequency of the delivery of the intervention. Just over half of the studies highlighted potential barriers to the facilitation of the cognitive stimulation programme. These barriers ranged from practical issues such as: feasibility of a long-term intervention, time commitment, difficulty in scheduling sessions, intervention not meeting staff expectations, and the additional demands put on staff. In addition to these barriers it was also reported in one paper that as a result of the attendees becoming more verbal and speaking more freely staff attempted to dissuade group members from attending

the intervention. However, this issue was subsequently resolved and staff members then fully cooperated with the programme.

3.8.7 Manager support

Only one study made reference to 'Manager support' by providing positive feedback following the intervention as efforts were made to reschedule meetings and the intervention continued after their research involvement. Aside from this study no mention of manager involvement was referred to in the included papers.

3.8.8 Employee support

Just over half of the studies provided information on the required level of 'Employee support'. However, a partial score was assigned to two studies for mentioning staff or aide, and family carer without providing further detail.

3.8.9 Resources

Very few studies provided a comprehensive report of the resources required to deliver the intervention. Six studies detailed the materials required to deliver the intervention (e.g. blackboard, clock), and numerous studies detailed some form of training received by the person delivering the intervention. Yet, there were no mention of training costs associated with this.

The training materials varied across the studies from demonstrations, discussion, handouts, videos and role-play. Six of the 20 included studies made reference to a manual. Three studies received a partial score as one manual was in press at the time of the article being published, and two studies provided no details as to what the manual included or where it could be sourced. The other three studies provided details on sourcing the manual so were assigned a maximum score. Only six studies provided information relating to the sourcing of materials to run the programme.

3.8.10 Population characteristics

All the included studies provided information regarding the population characteristics that the intervention was targeting. However, two studies were assigned one point due to missing some of the following criteria to receive a maximum score; (1) type of dementia, (2) exclusion criteria, (3) level of impairment, (4) intervention setting, (5) age range, (6) gender, (7) ethnicity, and (8) country of residence.

Only two studies made reference to who benefited most from the intervention. Breuil and colleagues (1994) identified that a lower educational level linked to a higher gain after stimulation, and Spector et al. (2003) identified that women benefited more than men from participating in the programme. The remaining 18 studies made no mention of who benefited most.

3.9 Grading of reporting

A total score of 52 could be attained for each included study. After applying the 'ImpRess' scoring the scores ranged from a minimum of 11 (Baldelli et al., 2002) to a maximum score of 29 (Chapman et al., 2004; Spector et al., 2003) (Table 3.2). No study excelled in the reporting when considering the potential maximum score. It is clear that the pragmatic considerations including planning consultation, manager support, employee support and resources were the most overlooked aspects in the reporting of studies. All of these considerations relate to implementation readiness of an intervention and are important to consider when putting a cognitive stimulation programme into practice.

Table 3.2: Score for included studies when applying the 'ImpRess' scale

Studies	Theme										
	Motivation	Theory of change	Implementation context	Experience	Planning consultations	Delivery collaborations	Manager support	Employee support	Resources	Population characteristics	Total
Akanuma et al., 2011	4	7	4	2	0	2	0	2	0	2	23
Baines et al., 1987	3	7	4	4	0	3	2	2	5	2	32
Baldelli et al., 1993	2	5	1	1	0	2	0	0	0	2	13
Baldelli et al., 2002	2	4	1	0	0	2	0	0	0	2	11
Bottino et al., 2005	2	7	3	0	0	2	0	0	0	2	16
Breuil et al., 1994	0	6	3	2	0	3	0	0	1	3	18
Buschert et al., 2011	6	7	4	2	1	3	0	0	2	2	27
Chapman et al., 2004	4	7	4	3	0	3	0	1	5	2	29
Coen et al., 2011	7	4	3	3	0	3	0	2	3	2	27
Ferrario et al., 1991	1	5	1	1	0	3	0	0	0	1	12
Gerber et al., 1991	0	5	4	0	0	2	0	0	1	2	14
Graessel et al., 2011	2	8	4	1	1	2	0	1	2	2	23

Hanley et al., 1981	2	5	3	3	0	2	0	2	4	2	23
Maci et al., 2012	4	5	4	2	0	2	0	2	1	2	22
Onder et al., 2005	4	5	4	2	0	3	0	2	4	2	26
Requena et al., 2006	1	7	3	0	0	2	0	0	1	2	16
Spector et al., 2001	2	7	4	2	2	4	0	2	4	1	28
Spector et al., 2003	2	7	4	2	0	4	0	2	4	4	29
Wallis et al., 1983	2	5	3	3	0	2	0	2	1	2	20
Woods et al., 1979	2	6	3	3	0	3	0	2	5	2	26

3.10 Applying the 'ImpRess' scale to other cognition based therapies

To determine if the 'ImpRess' scale (Figure 3.1) could rate the reporting of other cognition based therapies the scale was applied to a cognitive training (Niu et al., 2010) and cognitive rehabilitation (Buettner et al., 2011) study. These two papers were chosen as they came up in the original search but were excluded, as they did not meet the definition of cognitive stimulation.

3.10.1 Cognitive training

Niu and colleagues (2010) clearly evidenced the use of the primary outcome. However, for the secondary outcome measure only a partial score was given as the scoring was not detailed in the paper. Within the paper no mention was given to qualitative, organisational, or cost effectiveness information. So, the paper received a score of three out of 10 for 'Motivation'. The defined outcome measures used in assessing the cognitive training intervention were unclear so a partial score was assigned for this question, whereas a full score was given for describing the intervention, suitable design and providing a sound theoretical base, so 'Theory of change' attained a score of seven out of eight. A full score (four) was assigned for 'Implementation context' as the paper provided sufficient information in relation to the standardised package and included information for widespread implementation. In terms of level of 'Experience' a 'trained activity therapist' was mentioned within the text so a full score of two was assigned. However, only one point was given for monitoring as the attrition rate was stated but no further explanation was given in relation to attendance to the programme. The paper made no mention to the planning or setting up of the programme, so it scored zero for 'Planning consultations'. However, it clearly stated the time required in order to deliver the intervention, but no potential barriers were identified, so the paper received two for 'Delivery collaborations'. In regards to 'Manager support' and 'Employee support' alike no mention was made so both scored a zero for these themes. 'Resources' required in the

delivery of the intervention, training costs, training materials and sourcing of materials were not mentioned and there was no mention of a manual, so a score of zero was given. The sample was well explained in the paper but no additional information was provided as to who benefits most, so a score of two was assigned for 'Population characteristics'. The study lacked information in relation to the themes 'Planning consultations', 'Manager support', 'Employee support' and 'Resources'. Niu and colleagues (2010) in their paper detailing cognitive training received an overall score of 21 out of 52. However, this was a mid range score when compared to the scores achieved for the included cognitive stimulation studies.

3.10.2 Cognitive rehabilitation

Buettner, Fitzsimmons, Atav, and Sink., (2011) scored full marks in the reporting of the primary and secondary outcome measures. The authors did not provide any information in relation to the qualitative, organisational benefits, or cost effectiveness of the intervention. So, a score of four was assigned for 'Motivation'. The defined outcomes, description of the intervention, suitable design and theoretical base were all clearly defined and so the paper received a full score of eight for 'Theory of change'. In relation to implementation context the paper provided enough information detailing the standardised package and implementation in to practice. A complete score of four was given for 'Implementation context'. The 'Experience' of the person was not described in detail, although there was mention to the authors using the intervention in clinical practice. Reference was also made to the attrition rate, but no further detail was given so a total of two was given for 'Experience'. No mention was made to the planning or setting up of the sessions so the paper scored zero for 'Planning consultations'. Time assigned to deliver the intervention and barriers in the delivery of the programme were clearly stated, so a total score of four was given for 'Delivery collaborations'. Within the paper no mention was made to the

required ‘Manager support’ or ‘Employee support’, so a score of zero was given for both these themes. A manual was mentioned for the delivery of the programme, but no additional information was provided in regards to the materials required to deliver the intervention, so the paper scored two for ‘Resources’. The sample was well defined in the paper but no additional information was given in relation to who benefits most, so a score of two was given for ‘Population characteristics’. The study lacked reported information on ‘Planning consultations’, ‘Manager support’ and ‘Employee support’. Buettner et al. (2011) in their paper on cognitive rehabilitation received a total of 26 out of 52, and scored in the mid range of the ‘Impress’ scale.

3.10.3 Scoring for cognition based therapies

Applying the ‘ImpRess’ scale to cognitive rehabilitation and cognitive training demonstrated a similar level of reporting to the included cognitive stimulation studies. Both papers scored in the mid range for reporting of the intervention, and highlighted the potential applicability of the ‘ImpRess’ scale to other cognition based therapies.

3.11 Readiness for implementation grading

To extend this literature review further, after having evaluated the papers in terms of the level of reporting, the extent to which it can be implemented was looked at. In order to carry this out ASt, MO and ASp revised the scale, as each theme and corresponding questions were considered to determine what were the most important factors when considering the implementation of an intervention. After the ‘ImpRess’ scale was reviewed ASt, MO and ASp considered ‘Clinical effectiveness’, ‘Cost effectiveness’, ‘Training package’ and the ‘Standardised package’ as key factors to determine whether the intervention was ready for dissemination. The key questions were can the intervention be lifted from the paper and applied in a care setting, and be of benefit to the organisation, and individual. However, after reviewing the information

within the papers cost effectiveness was dismissed as a key factor. If retained for this section of the review, papers would have been marked down for not reporting on cost effectiveness, instead of demonstrating that the intervention not to be cost effective. A lack of reporting on cost effectiveness and not being cost effective are two different issues, so to be consistent in the grading of the papers it was excluded in the marking. If any of the papers reviewed the same intervention the most recently published paper was scored. In this instance Coen and colleagues (2011) emulated a study on a specific intervention of CST leading on from the Spector and colleagues (2001, 2003) research, and so this paper was marked when considering readiness for implementation.

In terms of clinical effectiveness the intervention had to demonstrate effectiveness for the main outcome measures. When applying this to this particular review the outcomes generally focused on cognition, QoL, and behaviour. Clinical effectiveness was an important factor to consider the purpose of delivering an intervention, as there should be a measurable benefit for the person involved. Otherwise, it could be argued that there is no point to delivering the intervention.

The second factor considered important in implementation was the mention of a training package in the form of a training day or published manual. To have a readily available training day or manual was considered key to ensure that the programme could easily be followed and adhered to. Without either of these training options it might be unfeasible to expect a person to implement an intervention correctly with a lack of guidance. If either training options were stated but no further detail was provided or could not be easily located (e.g. internet search), then the study was considered to be lacking enough detail to mark it as having met the criteria for this part of the grading.

For the intervention to be considered standardised it required enough detail to be provided, including timeframe and frequency in the delivery of the programme. This is an important factor to ensure that any two people can deliver the programme in the same way. In turn, this would maintain the standardised nature of the intervention.

3.11.1 Scoring of implementation readiness

Each study could obtain a minimum score of zero and a maximum score of three. For each of the three factors the study scored zero if they did not meet the requirements, and one point if they did demonstrate the factor. If the factor was partially answered a half point was given. A grade C was assigned for studies scoring one or below, and suggested the intervention was not ready to implement. Grade B was assigned for studies that scored between one and a half to two points, as it was considered partially ready to implement. Grade A was given to studies that scored between two and a half to three points, and were deemed ready to implement.

3.11.2 Results of implementation readiness

3.11.2.1 Clinical effectiveness

In terms of ‘Clinical effectiveness’ the primary outcomes measures were considered key in demonstrating benefit for the person with dementia. Out of a total of 18 studies, 13 papers reported positive benefits for their stated primary outcomes. The remaining five studies were given a half score of 0.5 as they demonstrated the benefit for only one of the key outcome measures.

3.11.2.1 Training package

The ‘Training package’ was required to consist of a manual or training day. Five studies made reference to a training day, but no formal training day was referenced or easily locatable so was considered insufficient for implementation. Two studies mentioned the use of a manual within the

text. One study scored one point for referencing a manual, whereas the other manual could not be located, and so for that reason the paper scored zero. The remaining 11 papers made no mention of a training package used to train the person in how to implement the intervention.

3.11.2.2 Standardised package

All 18 studies provided detail relating to the frequency and duration of the cognitive stimulation intervention. Consequently, for 'Standardised package' all studies were awarded a maximum score of one.

3.11.2.3 Overview of implementation readiness

In total 18 papers were scored on implementation readiness. Three papers reported on the same intervention, and so the most recent publication on this specific version of cognitive stimulation was used. One paper attained a grade A, and the remainder of the studies attained a grade B. The attainment of a grade B was expected for the majority of studies as information on 'Clinical effectiveness' and 'Standardised package' were expected to be written in the text, however a detailed 'Training package' was expected to be less reported on. This is a key factor to consider, when determining if an intervention is ready for widespread dissemination and implementation.

3.12 Discussion

There was a 43% reporting rate when the 'ImpRess' scale was applied across the 20 included studies. Falling below 50% in the reporting of readiness for implementation indicated the lack of reporting, including information related to getting the intervention in to practice. Given that the reported interventions might not be at the implementation stage and widespread dissemination this is not wholly unexpected. However, the improvement in the reported delivery of studies would heighten the likeliness of interventions being successfully implemented in real life settings and more quickly. For this to occur the reporting of studies is

required to provide enough detail to encourage the implementation of an intervention.

Studies adequately reported on the primary outcomes and provided evidence to support the use of these. However, the choice of secondary outcome measures was not so well supported. No studies provided qualitative benefits, or if mentioned was anecdotal and few studies offered organisational benefits or cost effectiveness, so this reduced the overall reporting percentage. Arguably, a qualitative perspective on the intervention is just as important as the quantitative perspective to gather information that outcome measures might miss. However, it might be that a qualitative perspective was not considered necessary to be written in the reported RCT studies. If qualitative work had been undertaken then the reporting of it would likely be reported separately as part of evaluation of the intervention (after or during the delivery of the programme) but it was not possible to investigate this further. To extend the scope of the 'ImpRess' measure to include cited or referenced papers would minimise the risk of missing this information.

There was a higher reporting rate for 'Theory of change' and 'Implementation context'. Arguably, this is to be expected due to the standard format in the reporting of studies as items such as outcome measures and standardisation of the intervention should be adequately reported. There was a lack of detail regarding the level of experience required by the person to deliver the intervention with reference made to 'aide' and 'staff'. However, generally no further detail was provided making it difficult to determine the level of experience necessary to run the programme. This information could be an important factor as a certain level of training may be necessary in the successful delivery of the intervention. There was also a lack of reporting on the attendance and adherence to the programme, as only two studies provided sufficient information. Despite that seven studies reported on the number of

dropouts, this did not provide additional information useful to the implementation of the programme. If comprehensive details in relation to level of experience were detailed in academic papers this would allow for an easier pathway from research into practice.

In regard to 'Planning consultations' the time required for the planning and setting up of the sessions was hardly reported across studies. As the included papers were RCTs the cognitive stimulation programme might not be at the stage of widespread implementation. Nonetheless, excluding this information limits its application as it can have cost implications in the delivery of the intervention. Leading on from this the time required to run a session and potential barriers were reported more frequently. Providing sufficient information in relation to the set up and delivery of the programme can allow for problem solving prior to the implementation of the intervention. Considering the practicalities of implementation is key to a successful programme and it is important for studies to report on this.

There were higher reported levels of 'Employee support' than 'Manager support' in the reported studies. This difference can be accounted for as in most instances there was a level of staff member involvement in the delivery of the programme. However, when taking into account the delivery and sustainability of an intervention, managerial support is advantageous to the successful implementation in the workplace.

The reporting of 'Resources' across studies was minimal. No studies reported on training costs to deliver the cognitive stimulation programme. If training was required prior to the implementation of the intervention this could act as a restriction due to the associated costs. Across all studies there was also a lack of information in relation to the training materials required and referencing of manuals used to deliver the programme. This

limits the ease to which the reported intervention can be implemented into practice.

All studies adequately reported on ‘Population characteristics’. However, few studies reported on who benefited most from the intervention. It may be possible that the reporting of this information would not be included in the published paper. The question of who benefits most can only be answered when the intervention has a strong evidence base and has been well researched. Therefore, it would be have been useful to widen the scope of the ‘ImpRess’ scale to consider additional published papers that reported on the same intervention to gather this information.

It was important in the development of the ‘ImpRess’ scale that under each theme heading the included questions provided sufficient detail in order to highlight the interventions readiness for implementation. Yet, it was also important to consider the time-consuming nature commonly found with a qualitative approach. By using the newly devised scale specific to psychosocial interventions the reader can look at the broader context surrounding the programme and hone in on specific factors that might hinder the implementation of this (e.g. lack of manager support).

To extend the systematic review to consider ‘readiness for implementation’ instead of grading reporting alone, a pragmatic approach was taken by identifying the same intervention being reported and evaluating the most recent paper. This was considered a logical step as it was expected that references would be made to the original research in the most up to date published version of the intervention. The version of cognitive stimulation that scored a grade A had three papers that were included in the systematic literature search. This demonstrated that the more evidenced based version of cognitive stimulation scored higher on implementation readiness. It was considered that the remainder of the papers fell in the grade B category and could be partially implemented.

This indicated the papers were not necessarily written with widespread implementation in mind.

The included studies were carried out over a 34 year period, between 1979 and 2013, and yet there was no increase in the reported scores over this timeframe. A higher reporting score for more recent studies was expected due to the recent dementia guidelines, current focus in dementia care, numerous reporting frameworks and the positive use of psychosocial interventions, specifically cognitive stimulation, but this was not seen.

3.12.1 Limitations

The potential limitations in the reporting of the included studies might indicate the restrictions placed on the authors when submitting research for publication. For instance, the word count may restrict the authors from elaborating further on the contextual information necessary to be presented in the paper to fully understand the rationale behind the methodology they chose. In addition to this if the focus is on the effect of the intervention on participants, in this instance people with dementia, it may be deemed unnecessary to include additional information. Available information in relation to training and delivery of the intervention by the staff member or member of the research team might be available but not suitable in the reporting of the RCT.

Particular themes, such as, ‘Manager support’ may provide a lack of information in the text due to unspoken acknowledgement that managers are aware of the intervention taking place due to the research activity. So, the necessary level of support may be there, but does not need to be stated within the text. In a similar thread the lack of reported support from employees may be due to the delivery of the intervention being undertaken by a researcher. As no additional support would be required it would be unnecessary to report this within the paper. Similarly, the

question who benefits most for ‘Population characteristics’ would not have necessarily been considered to highlight a particular subgroup of the targeted population as all the studies were conducted as RCTs. In addition to this if there were significant findings for the intervention group as a whole it could be argued this is benefit enough.

Qualitative feedback was anecdotal and provided by the authors in the discussion section. Consequently, this needs to be interpreted with some level of caution due to the subjective nature of the reporting. In addition to this the cost effectiveness and recommendations of cognitive stimulation was only identified in 2006 (Knapp et al., 2006; NICE, 2006) so the reporting of this information within papers would not have been possible prior to this date.

In terms of grading for implementation readiness it is important to note that the papers were not written necessarily with widespread implementation in mind. So, details might be disregarded as not useful in the reporting of the RCT. However, this makes it difficult when considering ease of implementation, as there is a lack of detail in the reported papers.

ASt carried out the screening, grading and reporting of included studies. Although an effort was made to seek clarification where necessary further validation and reliability testing of the scale is required.

3.12.2 Implications for practice

This systematic review highlighted the lack of reporting in relation to implementation. The information provided within the included studies tended to provide a shallow account of the setting up and implementation of cognitive stimulation. On occasion the information was difficult to extract from the text and left the answers for some of the questions in the ‘ImpRess’ scale open to interpretation. Similarly, this was reported in the

original paper that the themes were lifted from (Egan, Bambra, Petticrew, & Whitehead, 2009).

Arguably, researchers should consider the reporting of interventions within academic papers to promote the implementation phase, as this is crucial in the design and evaluation of interventions. For the purposes of this review it was applied to cognitive stimulation but can be applied to other interventions when taking in to account the need for successful dissemination in practice.

In order to effectively use the 'ImpRess' scale to determine how far an intervention is ready for implementation in practice, it is useful to bring together the specific group of papers covering the most comprehensive picture available. This may include papers on development work, economic analysis and implementation studies. In practice the evaluation of psychosocial programmes using the 'ImpRess' scale may deliver substantial benefits for health and social care providers, as currently there is a lack of clear reporting in to the delivery of interventions for people with dementia, especially interventions directly provided by healthcare professionals instead of the research community.

When considering 'readiness for implementation' researchers can use the 'ImpRess' scale to evaluate research implementation or as a guide to reporting cognitive stimulation and this may increase the likeliness of the intervention being used in practice. By making it easily accessible as opposed to keeping it in the research sphere of academia can encourage the public dissemination of positive and useful research findings.

3.13 Conclusion

This systematic review highlighted the need to report findings to a high standard, but to also consider the reporting of information related to implementation that can heighten the uptake of cognitive stimulation. By

considering the dissemination and long term implementation of CST provides an opportunity to consider the barriers and pragmatic reasons for a lack of uptake of the therapy.

This systematic review on the 'readiness for implementation' of cognitive stimulation highlighted the lack of information supplied in academic papers for further dissemination into practice. To develop the 'ImpRess' scale further when considering specific interventions, would be to do a thorough evaluation including the citations in a paper. An attempt at this was made when combining three of the CST papers together when considering the 'readiness for implementation'. In addition the 'ImpRess' scale was applied to cognitive rehabilitation and cognitive training to demonstrate its suitability when looking at the reporting of other cognition based therapies.

Although there a numerous frameworks there are currently no set guidelines as to what is necessary to include in published research to increase the uptake of psychosocial interventions, and there is still a need to improve details reported across journals. Until a consensus is reached as to the level of information required when detailing an intervention there is likely to be a gap between research and successful dissemination in practice.

Chapter 4: Implementation of maintenance CST in practice: a randomised controlled trial in two streams

4.1 Introduction

The gold standard in evidence-based medicine is a RCT. The next stage is to consider the implementation and dissemination of the research findings in practice. This stage is particularly useful when considering the continuing contribution of the intervention outside of the research environment, as highlighted in the previous chapter.

In healthcare related professions there is a well-documented gap between research findings and their application in practice (Grol & Grimshaw, 2003). Traditional dissemination includes publishing in a peer-reviewed journal, individual sourcing, and appraising before applying the evidence in everyday practice (Grimshaw, Eccles, Walker, & Thomas, 2002). Numerous reasons have been given for the failure in the successful dissemination of these, including passive dissemination (Bero et al., 1998), lack of training for professionals in appraising research findings (Grimshaw, Eccles, Walker, & Thomas, 2002), and external barriers to implementing change, such as structural, organisational, peer and individual factors (Grimshaw, Eccles, Walker, & Thomas, 2002). To overcome the aforementioned barriers the Cochrane Collaboration has synthesised current evidence with the aim to 'help people make well informed decisions about health by preparing, maintaining, and ensuring the accessibility of systematic reviews of the benefits and risks of healthcare interventions' (Bero & Rennie, 1995).

Previously conducted CST research has utilised the researcher as the main facilitator and a staff member as the co-facilitator. Subsequently, there is little evidence on the delivery of the programme outside of the research environment. This set up may also have limitations in the professional development of the staff member. Therefore, emphasis

should be placed on creating a learning opportunity for them to claim responsibility for the delivery, and outcomes of the programme. This 'ownership' in the delivery of the programme can then benefit them in a professional capacity and encourage widespread dissemination of the CST programme. This is particularly relevant due to the evidence base and current guidelines recommending the use of CST in clinical practice. Yet, currently there is a lack of research in regards to outcomes related to getting CST into practice. A recent study found that of the staff members who attended a CST training course all felt skilled enough to run the programme, but only a third of the respondents went on to implement CST groups in practice (Spector, Orrell & Aguirre, 2011). The respondents identified the need for management support, regular supervision, supervision from a specialist, online forum and additional training as useful in starting and running groups. To encourage the uptake of CST it was considered that additional support might increase the adherence to the programme. As a result, it was decided that additional outreach support would consist of (1) online forum, (2) email support, and (3) local supervision. This included monitoring of the programme to ensure that CST was delivered in the correct manner, and in turn provide positive outcomes for the person with dementia. The study was undertaken as part of the SHIELD programme, a five-year National Institute for Health Research (NIHR) funded project that aimed to reduce disability, increase QoL, and health outcomes for people with dementia and their family caregivers (Burnell et al., 2007).

4.2 Background to staff recruitment

Prior to undertaking the research it was acknowledged that each staff member would vary in level of CST experience. For this reason recruitment was split into the staff training and outreach (STANDOUT) and monitoring and outreach (MONOU) trials (Table 4.1). The STANDOUT trial delivered CST training to the staff members that were new to CST, having had no prior experience of using the therapy. In contrast, the MONOU

trial included staff groups who prior to the research had either received CST training or previously obtained the CST ‘Making a difference’ manual. The intervention of outreach support could then be applied to both parts of the trial to determine if there was an impact on the number of attendees (people with dementia) to the CST sessions offered.

Table 4.1: Overview of the STANDOUT & MONOU trials and Observational study

Title	**Staff training & outreach (STANDOUT) trial (staff new to CST)**	**Monitoring & outreach (MONOU) trial (staff familiar with CST)**	**Observational study (Chapter 6)**
Aim	To assess the effectiveness of staff training & outreach support.	To assess the implementation in practice of CST & effect of outreach support.	To assess the effectiveness of CST in practice for people with dementia.
Participants	Qualified and non-qualified dementia care staff new to CST.	Qualified and non-qualified dementia care staff with previous access to CST manual & some of whom received previous training.	People with dementia.
Number	175	66	89
Resources	CST manual, maintenance CST manual & DVD.	CST manual, maintenance CST manual & DVD.	CST manual, maintenance CST manual & DVD.
Training	Yes.	Some staff had training but not as part of study.	Some staff had training but not as part of study.
Outreach	50% (online forum, email support and local supervision).	50% (online forum, email support and local supervision).	Some staff had access to outreach support options.
Assessment schedule	Baseline, 6 and 12 months.	Baseline, 6 and 12 months.	Before and after CST (0,7 or 0,14 weeks) and after maintenance CST (31 or 38 weeks).

The STANDOUT and MONOU trial remained the same in that both trials recruited non-qualified and qualified dementia care staff, and had the same time points for the staff questionnaire. In terms of the intervention the outreach support options also remained the same as any staff member randomised to the intervention could access the online forum and email support. The only difference was the participants in the MONOU trial were expected to identify their own local supervision. This decision was made to replicate the practical issues staff might encounter when accessing additional support to implement the programme in practice.

4.3 Research question

Can offering outreach support in relation to CST, to qualified and non-qualified dementia care staff, impact on the implementation of the programme in care settings (number of sessions run) and number of attendees to the CST and maintenance CST programme?

4.4 Aim

The aim of the STANDOUT and MONOU trial was to evaluate the effectiveness of CST staff training and outreach support for non-qualified and qualified dementia care staff in care settings to improve the delivery of the CST programme in comparison to the control group (CST training or manual only). A cluster RCT design was considered the most appropriate due to small groups of staff being located in the same working environment. To randomise participants independently of one another would not have been feasible and heightened the risk of contamination across staff randomised into intervention compared to TAU.

4.5 Hypotheses

4.5.1 Primary hypothesis

The additional provision of outreach support over a 12 month timeframe will increase the number of sessions offered by the staff members' and increase the number of attendees to the CST and maintenance CST programme, as recorded using the monitoring progress in the CST manual (Spector, Thorgrimsen, Woods, & Orrell, 2006), in comparison to the control group.

4.5.2 Secondary hypotheses

The provision of outreach support will increase the adherence to the CST key principles when implementing the programme, as devised and amended from the maintenance CST trial. The provision of outreach support will also impact staff job satisfaction, approach to dementia, dementia knowledge, sense of competence, learning characteristics, barriers to change within the workplace, and the controllability of challenging behaviour in people with dementia.

4.6 Ethical, site approval and trial registration

4.6.1 Ethical approval

East London Research Ethics Committee (REC) 3 first approved the study on the 14th June 2011 (Appendix 1.1), REC reference 11/LO/0059. The original approval letter missing the deletion of a consent form that the REC considered irrelevant at the time of submission, so the approval was re-issued on the 12th July 2011 (Appendix 1.2).

4.6.2 Site approval

A Trust was able to nominate themself to participate in the research due to the study being on the Dementias and Neurodegenerative Diseases Research Network (DeNDRoN). Otherwise, contact was generally made with ASp, and initiated by a lead within the Trust, to provide a commercial CST training day. For the duration of the research study time period

people who expressed an interest in receiving CST training were approached by ASp and ASt to determine their level of interest in receiving CST training as part of a research study. ASt was then able to have a telephone conversation with the necessary person to further explain the purposes of the project, and the required inclusion criteria. If this person felt that the Trust was able to meet the inclusion criteria an SSIF was then submitted to the relevant Trust before any further action was taken. A local collaborator (LC) or Principle Investigator (PI) was identified for each site and for the majority of sites this tended to be the person who made the initial contact for the Trust to receive the CST training day. When the site approval was granted the relevant managers were approached and received the manager information sheet (Appendix 3.4), the training day was then organised, and the information sheets and consent forms were sent to the potential participants. After having read the information sheet (Appendix 3.2; Appendix 3.3) the staff member would then state if they met the inclusion criteria and were in principle, happy to consent to participate in the research. Prior to the delivery of the training day the consent form and BL questionnaire were completed by each staff member recruited into the STANDOUT trial. For the STANDOUT and MONOU trial a Site Specific Identification Form (SSIF) was completed for each Trust and approval was gained from the local Research and Development (R&D) department.

4.6.3 Trial registration

The trial was adopted by DeNDRoN and co-supported by the Mental Health Research Network (MHRN). It was submitted for inclusion on the International Standard Randomised Controlled Trial Number (ISRCTN) register and assigned the trial identification number: ISRCTN28793457.

4.7 Method

4.7.1 Study design and rationale

The design was a pragmatic, multi-centre, single-blind, two treatment arm, RCT. All of the participants in the STANDOUT trial received the training package as TAU, that consisted of the one day CST training, training DVD, CST manual and maintenance CST manual. All of the participants in the MONOU trial received the maintenance CST manual as well as the accompanying staff training DVD. The participants in the intervention group (STANDOUT & MONOU) also received the outreach support options (local coordinator, email support and online forum). The sample was dementia care staff members' from specialist and non-specialist dementia care settings.

Prior to the training day the staff members' in the STANDOUT trial were then cluster randomised according to place of work to receive outreach support or TAU. Each staff member was expected to complete three questionnaires, before the training day, and at six and 12 months thereafter. The staff members participating in the MONOU study were randomised on entry into the study after completion of their BL assessment.

4.8 Development of the staff training programme

4.8.1 Outreach support

Interventions considered to be effective in promoting behavioural change amongst healthcare professionals include manual reminders, multifaceted interventions, and interactive educational meetings (Bero et al., 1998). Additional support of variable effectiveness includes audit and feedback, local opinion leaders, consensus processes, and patient mediated interventions (intervention aimed at changing performance of healthcare provider with specific information sought from or given to patients)(Bero et al., 1998). However, the development of the outreach support options

were driven by the feedback received from the pilot study examining the use of CST after the one-day training (Spector, Orrell, & Aguirre, 2011).

4.8.2 Online forum

The online forum was an online discussion site. This was designed, developed and maintained by ASt. The content of the forum was taken from the frequently asked questions in the Maintenance CST 'Making a difference 2' manual. This was considered useful to encourage people to build on the answers previously stated in the manual and prompt people to think of new ideas and queries. It was accessible by user name and password. The first time a person attempted to enter the site, an email was sent to ASt for approval in order to ensure they have been randomised to the outreach support (intervention group). The use of a login recorded the number of times people accessed the service. The staff members' had the option to write up a variety of messages ranging from comments on sessions, to questions and advice.

4.8.3 E-mail support

Prior to the research study ASt had extensive experience of delivering both the CST and maintenance CST programme, so it was considered that ASt was suitable to offer email support. This service was made available to staff members' as much as was needed. If ASt felt unable to answer any queries raised then it was redirected to MO and ASp, as both are leaders in the development and evaluation of the CST and maintenance CST programme, and dementia care in general.

4.8.4 Local supervision

For the STANDOUT trial ASt provided the local supervision. For the MONOU trial a person familiar with CST and experience in running groups delivered the local supervision, ideally a Psychologist or Occupational Therapist. If a person was not identified this was recorded accordingly. The role of the local supervisor was to advise on the setting up of the CST

group and practical issues when attempting to run CST groups. The supervisors' recorded all the support given.

4.9 Participants

Each staff member was screened to ensure they met the inclusion criteria of (1) adequate written and spoken English, (2) able to complete online assessments at three different time points, (3) have at least two other team members to run groups, (4) agreement from their management to have time set aside per week to run the CST and maintenance CST groups, and (5) able to identify between five to eight people with mild to moderate dementia willing to participate in the programme. For logistical purposes a minimum of three staff members were recruited per centre, to be able to consistently run the groups. However, as a naturalistic study the MONOU trial differed in that a minimum of one staff member was required per centre, as any person that met the inclusion criteria and consented to the study was recruited into the trial.

4.10 Sample size rationale

For the STANDOUT trial a minimum of three staff members were recruited per centre. Up to 40 centres were required to be able to recruit the 120 staff members required for the trial. Due to the possibility of one person per centre up to 120 centres were needed to recruit the 120 staff members for the MONOU trial. In total 241 staff members were recruited across the two trials. Based on 80% power and intracluster correlation coefficient of 0.05, combining the 241 staff members from the STANDOUT and MONOU trial provided enough staff members in both the no outreach and outreach support groups (control and intervention groups) with an effect size of 0.4 at 5% significance to determine the feasibility of the trial.

4.10.1 Recruitment settings for STANDOUT trial

The STANDOUT trial had a total of 50 centres across North East London Foundation Trust, St Mary's Hospital Kettering, Tees, Esk and Wear Valleys NHS Trust, and Worcestershire Health and Care NHS Trust. As well as Olympuscare services, as part of Northamptonshire county council and Quantumcare limited, a not for profit organisation, with homes across Hertfordshire, Bedfordshire, and Essex. All the managers within these Trusts and organisations expressed a commitment to provide support for the staff member to deliver the CST and maintenance CST programme after the training day.

Participating centres were identified by approaching leads within each Trust or organisation that had expressed an interest in organising a commercial CST training day with ASp. The lead person was contacted by ASp to see if they were happy to be contacted by ASt in regards to the research project. If they agreed to this ASt then sent the lead person an e-mail detailing the project, including information sheets and inclusion criteria. If the staff members met the inclusion criteria and the project was of interest to them a telephone conversation was then held between the lead contact and ASt to determine, suitability of the Trust or organisation, their level of interest, commitment to the trial, ability to provide a sufficient number of staff members and people with dementia to participate in the CST programmes.

If the Trust me the inclusion criteria and this was agreed by the lead at the Trust, ASt completed a SSIF to gain Trust approval to conduct research in their area. In regards to the organisations that participated in the trial managerial consent was obtained before the training day took place. Prior to the training day cluster randomisation occurred. Cluster randomisation by centre was deemed necessary so that the staff member's from the same centre were in receipt of the outreach support or not. The number of staff members within each centre was also taken into account as by

pairing centres of a similar size minimised any potential imbalance between the control and intervention groups. In the STANDOUT trial the commercial CST training day, the CST 'Making a difference' manual, and the maintenance CST 'Making a difference 2' manual were given for free, as well as the offer of outreach support for the intervention groups.

4.10.2 Recruitment settings for MONOU trial

The MONOU trial comprised of 13 centres across North East London Foundation Trust, Worcestershire Health and Care NHS Trust, Kent & Medway NHS and Social Care Partnership Trust, North Staffordshire Combined Healthcare NHS Trust, and individual Care homes and voluntary organisation. Initially, in order to identify centres that qualified to participate in the MONOU trial ASt created two lists. One list was of the people who had purchased the 'Making a difference' manual in the past two years through Hawker Publications, and this amounted to 76 centres in total. This list was difficult to create as it was taken from individual receipts that were being stored in box files. The other list compiled by ASt was the people who had attended a commercial CST training day in the past two years. This information was gathered from paper records of individual registers taken from each training day. There was no guarantee that all registers were stored, but all the available registers were entered into an Excel spreadsheet. There were 267 contacts generated from this list. A number of people were excluded from being contacted on the list for the following reasons; 28 people were identified as not working directly with people with dementia, 31 people had previously participated in the MCST project (Aguirre, et al., 2010), and 11 people had no contact details. Overall, 197 individuals were contacted from this database.

Aside from these two avenues of recruitment adverts were also placed in Journal of Dementia Care, National Care Forum, Hawker Publications and the trial was also listed on DeNDRoN. Consequently, Trusts were able to approach the research team if they were interested in participating in the

trial. The screening of potential centres for the MONOU trial was identical to the STANDOUT trial.

4.11 Sample

For both the STANDOUT and MONOU trial once the Trust, organisation or individual centre became enrolled in the trial and the SSIF and the consent form had been completed by the manager (Appendix 4.2), and each staff member (Appendix 4.1), they were then recruited into the trial.

4.11.1 Inclusion criteria

4.11.1.1 STANDOUT trial

To be eligible to participate in the STANDOUT trial the following inclusion criteria was required to be met:

- Minimum of 3 staff members within each centre.
- Staff working directly with people with dementia.
- Adequate written and spoken English of staff member.
- Opportunity to recruit 5-8 people with mild to moderate dementia.
- Agreement for staff to complete three sets of questionnaires over a year time frame.
- Agreement with management to have time set aside to run the CST and maintenance CST programme and complete their questionnaires.
- For staff to have basic computer skills and access to a computer.
- Centre to have the intention to run the CST and maintenance CST programme.

4.11.1.2 MONOU trial

The MONOU trial had identical inclusion criteria to the STANDOUT trial, apart from a minimum of one staff member was required per centre. As it was run as a pragmatic trial, staff members who had previous experience of CST were considered suitable to participate in this arm of the trial.

4.12 Exclusion criteria

4.12.1 STANDOUT & MONOU trials

The staff member was excluded if they met the following criteria:

- Did not work directly with people with dementia.
- Unable to identify 5-8 people with mild to moderate dementia.
- Unable to deliver the CST and maintenance CST programme.
- Lack of managerial consent.
- Unable to complete three sets of questionnaires.

4.13 Screening staff members for eligibility

For the STANDOUT trial each Trust or centre lead was given the listed inclusion criteria and this was then distributed to every manager from each centre to determine whether they could meet these. Managers either nominated staff members within their centre, or asked each staff member to nominate themself. It was expected that a majority of the staff members would meet the inclusion criteria. It was considered that the main issue to overcome in recruiting the staff member is whether they were willing to participate in the study. As the therapy was not already being delivered in their care setting it would be in addition to their usual caring duties. Another concern was adequate staff provisions to enable the required number of staff members to attend the one day CST training day.

For the MONOU trial each individual that expressed an interest in participating in the trial was given the inclusion criteria, and if they worked with other members of staff who were familiar with CST they were able to participate also. In contrast to the STANDOUT participants, the staff members' in the MONOU trial already had some level of experience in delivering CST. In most instances the staff member was familiar with delivering the therapy, so it was not seen as a task in addition to their usual workload.

ASt provided advisory inclusion criteria to identify suitable people with dementia to participate in the CST programmes. This was based on the inclusion criteria for the participants in the observational study (Chapter 6), however it was not compulsory to follow.

4.14 Consent and information sheets

Information sheets and consent forms for both the STANDOUT and MONOU trials were created and approved by East London REC 3. ASt drafted the necessary consent forms and information sheets and MO, ASp and JH reviewed these to ensure they were clear and concise. The required changes were made until both forms were agreed upon. The information sheet differed between both the trials as the training day was omitted from the MONOU trial information sheet.

Each staff member received the consent form and information sheet before they agreed to participate in the trial, which allowed them time to ask any questions. Each staff member was then expected to read the information sheet online and had to tick each box on the consent form before they could enter the baseline assessment. In the STANDOUT trial the staff members' also completed a paper version of the consent form on the training day, whereas in the MONOU trial participants were sent the paper version and this was sent back in the post. This consent forms were then signed and dated by ASt, and held in a secure place at the researcher's place of work.

4.15 Measures and data collection procedures

4.15.1 Development of the online survey

Prior to the recruitment of participants into the trial the original measures were sourced and ASt entered each measure into the online survey tool, Surveymonkey. Two researchers within the SHIELD programme then checked that the measures and responses had been entered correctly,

and ASt then corrected any errors. The researchers also reported the time taken to complete the questionnaire as approximately 35-40 minutes. This was considered a manageable amount of time and so for this reason no measures were altered or excluded from the questionnaire.

4.15.2 Interview procedure

The staff member was able to nominate him or herself to participate in the STANDOUT or MONOU trials, and met the inclusion criteria. Each individual was then given a link to access the BL assessment, via Surveymonkey. The website also included the information sheet and an online consent form before the participant could enter and complete the survey. At this point potential participants had seen a paper version of both the information sheet and consent form and also viewed it online. This allowed the person plenty of time to familiarise themself with the project, what was required of them, and to ask any questions. If the person had difficulty accessing the online questionnaire, ASt gave them a paper version. This was more likely in care settings where there was limited access to the Internet. Each lead at the site and participants received a paper copy of the information sheet and a photocopy of their consent form.

4.16 Measures for staff

4.16.1 Primary outcome measure

The primary outcome measure was the number of attendees to CST and maintenance CST sessions run in each centre. This was recorded using the monitoring progress form located in the 'Making a difference' manual. This form included attendance, level of interest, communication, enjoyment and mood, on a rating scale that ranged from a score of one to five. The lowest score of one indicated a low level of interest, communication, enjoyment and mood for the person with dementia and a high level of engagement across these each category was demonstrated in a recorded score of five. This attendance measure was completed at

the end of each session from BL to 31 or 38 weeks (inclusive of maintenance CST), until the maintenance CST groups were completed, or until the facilitator discontinued the group. This record was completed in a booklet that was sent to each centre prior to them starting the group. This was in order to make it easy for participants to record and store the attendance and adherence of each group member.

4.16.2 Secondary outcome measures

4.16.2.1 Adherence

Level of adherence to the CST and maintenance CST programme was measured using an adherence checklist designed for this research study (Figure 2.2). This checklist was based on the 18 key principles developed as part of the maintenance CST programme. The development involved looking at the original key principles list and generating one question per principle for ease of completion. Bearing in mind that staff time was limited, it was important to minimise staff burden by creating an easy to complete and straightforward adherence checklist. ASt, MO, ASp and JH reviewed these questions, and amendments and formatting changes were made accordingly.

After completion of the CST or maintenance CST programme the attendance and adherence booklets were returned to ASt. All of the attendance records were entered into an excel spreadsheet to measure attendance for each centre. A third of the adherence records were entered onto the spreadsheet with five centres in the intervention and five centres in the TAU group, and six of those centres in the STANDOUT trial and four centres in the MONOU trial. The responses entered were reviewed by ASt to mark whether groups run were adherent to the key principles as laid out in the ‘Making a difference 2’ manual. Any ambiguity of responses provided was discussed with another researcher until a consensus was reached as to whether they were adhering to the key principle. If individual questions were not answered it was considered that

the session had not adhered to the key principle in question. If any of the adherence forms were missing for sessions this was recorded accordingly.

4.16.2.2 Minnesota Satisfaction Questionnaire

The Minnesota Satisfaction Questionnaire (MSQ; Weiss, Dawis, England, & Lofquist, 1967) is a self-administered questionnaire that measures job satisfaction looking at the different aspects of work that the person does and their work environment to determine the persons level of job satisfaction (Appendix 5.1). The MSQ is made up of 100 questions and comprises of 20 dimensions. The 20 dimensions are made up of the following: ability utilization, achievement, activity, advancement, authority, company policies and practices, compensation, co-workers, creativity, independence, moral values, recognition, responsibility, security, social service, social status, supervision (human relations and technical), variety and working conditions. There is also an additional scale of overall satisfaction. There are five items per scale on a five-point Likert rating scale: very dissatisfied, dissatisfied, neither satisfied nor dissatisfied, satisfied and very satisfied. Very dissatisfied equates to one point and very satisfied as five points, so a minimum score of 100 and maximum score of 500 can be achieved. A percentile score of 75% or over indicates a high level of job satisfaction, a percentile score of 25% or lower suggests lower job satisfaction, and those in the middle range indicates average job satisfaction.

The long form was decided upon as this version is recommended by the authors of the measure, and should take no longer than 20 minutes to complete. The measure has adequate internal reliability and validity (Weiss, Dawis, England, & Lofquist, 1967).

4.16.2.3 Approaches to Dementia Questionnaire

The Approaches to Dementia Questionnaire (ADQ; Lintern & Woods, 1996) is a 19-item questionnaire using statements about the person with dementia, such as 'people with dementia often have good reasons for behaving as they do' (Appendix 5.2). Answers range on a five-point Likert scale from 'strongly agree' to 'strongly disagree'. The total sum of these scores can be calculated ranging from 19 – 95, and can also be calculated to include subscales for hope and person-centeredness. The scale has high validity and good reliability using Cronbach's α, and has good retest reliability (total 0.76, hope 0.70, and person-centred 0.69). The ADQ was used in a previous study that looked at staff attitudes and QoL in care homes for people with dementia. The authors found that care staff with higher levels of hope were associated with higher levels of QoL as rated by the care home residents (Spector & Orrell, 2006). Specifically, it is the hope subscale that seems to predict staff behaviour, which is why the measure was considered useful to include in the research, as this might indicate whether a person is likely to run the CST programme or not.

4.16.2.4 Dementia Knowledge – 20

Knowledge was measured using the Dementia Knowledge–20 (DK-20; Shanahan et al., 2010) questionnaire (Appendix 5.3). The DK-20 aims to gain an understanding of staff member's knowledge and approach to caring for people with dementia. There are 20 questions for which there are five possible answers, but only one answer is correct. There is a minimum score of zero and a maximum score of 20. The measure can be split into two sub-themes dementia core knowledge and dementia care knowledge. Within dementia core knowledge there are two sub-domains, general knowledge and behavioural and psychological symptoms of dementia. Within dementia care knowledge there are six sub-domains: person-centeredness, communication, psychosocial interventions/activities, managing challenging behaviour, risk and abuse

prevention, and consent and decision-making. The scale has sufficient reliability and demonstrates a correlation with the ADQ (Lintern & Woods, 1996). This measure was administered at BL and FU2 only, to see if the participant's knowledge changed over the timeframe of the trial.

4.16.2.5 Sense of competence in dementia care staff scale

Perceived sense of competence was measured using the sense of competence in dementia care staff scale (SCIDS; Schepers, Orrell, Shanahan, & Spector, 2012). It comprises of 17 items categorised into four subscales: professionalism, building relationships, care challenges and sustaining personhood (Appendix 5.4). It is designed to be completed by untrained frontline dementia care staff. The competence measure is phrased as 'how well do you feel you can…' and asks questions such as 'engage a person with dementia in conversation' and answers range on a four point Likert scale from 'not at all' (1) to 'very much' (4). The scale has good internal consistency and moderate test-retest reliability, and the measure has positive associations with work experience, job satisfaction and person-centred approaches in dementia care, that could indicate validity of the measure. The measure is a useful tool for the research to indicate the level of competency the staff member has in relation to their job role, that could impact on the implementation of the programme in the staff member's workplace.

4.16.2.6 Learning Transfer System Inventory (brief form)

Learning characteristics of staff was measured using the brief Learning Transfer System Inventory (brief LTSI; Spector, Orrell & Aguirre, 2011) (Appendix 5.5). The original measure (Holton, Bates & Ruona., 2000) is a 66-item questionnaire that can be grouped into 16 constructs, and four main groups; trainee characteristics, motivation, work environment and ability (Holton, Bates & Leimbach, 1997). The constructs of the LTSI are validated using common factor analysis (Holton, Bates & Leimbach., 1997; Holton, Bates, Seyler, & Carvalho., 1997). The brief form comprises

of one question for each of the 16 factors that was devised from the original paper. The measure considers learning transfer in public, private and voluntary organisations, and so was relevant for the demographic of staff that were recruited into the trial. This measure is also useful in identifying training needs, and as an evaluation tool for training policies. The scale uses a five-point Likert-type scale from one (strongly disagree) to five (strongly agree).

4.16.2.7 Barriers to Change Questionnaire

The Barriers to Change Questionnaire (BARCQ; Corrigan, Kwartarini, & Pramana., 1992) looks at the belief that a person has of training being introduced in to the workplace (Appendix 5.6). The scale measures institutional constraints, support from colleagues, philosophical opposition, client dissatisfaction, interference, and positive factors. It includes statements such as, 'there are too many clients' and 'I don't believe the training will work with clients'. It is a 19-item questionnaire ranging from not a barrier at all (0), a very slight barrier (1), a small barrier (2), a modest barrier (3), a large barrier (4) and an insurmountable barrier (5). A minimum of zero and a maximum of 80 can be scored on the measure. It also allows the person to rate three helpful factors to aid the implementation of training, as well as additional comments. The need to identify and address barriers has been previously identified (Cheater et al., 2005) and so the BARCQ was considered a useful tool to identify any perceived barriers that staff were already experiencing in their job role, or any barriers in the process of running the CST or maintenance CST programme.

4.16.2.8 Controllability Beliefs Scale

The Controllability Belief Scale (CBS; Dagnan, Grant, & McDonnell., 2004) measures the emotional and behavioural responses related to the person's thoughts about challenging behaviour demonstrated by the person with dementia (Appendix 5.7). The scale has 15 items such as,

'they are trying to wind me up' and 'they are not to blame for what they do' and is based on a five-point scale from 'agree strongly' to 'disagree strongly'. Higher scores indicate the staff member believes the level of control demonstrated by the person with dementia is high. The scale has good internal reliability.

4.16.2.9 Demographic data

Socio-demographic information was also collected such as the geographical location, centre name, type of centre, and specialist dementia care setting. The gender, age, level of experience, highest qualification, and ethnicity of each participant was also collected. The collection of this additional information allowed a comparison between centres and individual characteristics.

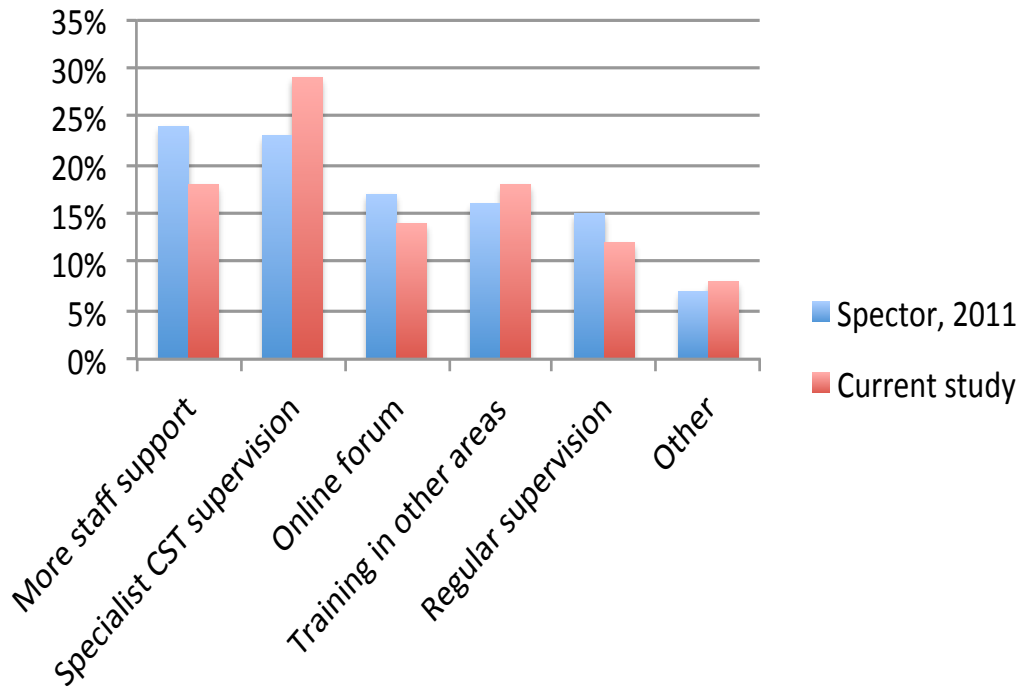
4.17 Previous CST use: MONOU study only

The retrospective questionnaire was completed with participants in the MONOU trial only. The retrospective questionnaire was partially lifted from a pilot study by Spector and colleagues (2011) examining the use of CST after a one day CST training day. It was created as two forms, one form for staff that have attended the CST training day and the second form for staff that have purchased the CST 'Making a difference' manual only. The purpose of the questionnaire was to collect each participant's previous use of CST, and was considered beneficial to gauge the staff member's previous experience of CST. The questionnaire asked whether the training or manual had given them enough information to run the programme, and what they considered beneficial to aid implementation. The responses given were then compared to the Spector et al. (2011) pilot paper.

In the MONOU trial 20 participants were in receipt of the training, and the remaining 46 participants experience of CST was through the use of the CST 'Making a difference' manual only. Participants were asked to

complete the questionnaire at the beginning of the trial, but this was not a prerequisite to participating in the trial. Forty four (67%) of the 66 participants responded to the retrospective questionnaire, and 38 (86%) respondents felt that the training day or manual equipped them with the necessary skills to implement the programme. Respondents were asked what they considered beneficial to run the programme from the following options: support group for staff running groups, supervision from a CST specialist, online forum, training in other areas related to dementia, supervision from management or other. Of the responses 14 (29%) answered regular supervision from a CST specialist, nine (18%) stated support group for staff and for training in other areas relating to dementia (18%), seven responses to access an online forum (14%), and six responses of regular support from management (12%). In the additional comments section four respondents (8%) asked for access to basic training, training in relation to people with severe dementia and ad hoc peer supervision. Comparatively, Spector and colleagues (2011) reported support from other staff (24%), specialist supervision (23%), online forum (17%), training in other areas relating to dementia (16%), regular supervision (15%) and other (7%) including support and learning from colleagues, group facilitator training, facilitators experience in running groups, understanding the group and work flexibility (Figure 4.1).

Figure 4.1: Graph demonstrating difference between current study and previous study staff preferences for outreach support to run CST programme



Spector et al. (2011) and the current study reported similar responses in regards to the additional support considered beneficial to implement the CST programmes. However, the respondents from the MONOU trial favoured CST supervision over more support from other staff members.

The Spector et al. (2011) study also asked respondents to complete the ADQ and brief LTSI, and compared those that run CST compared to those that did not. The respondents who ran CST also scored significantly higher on the brief LTSI suggesting that they had effective learner characteristics, work environment and ability/enabling. The authors concluded that learner readiness and performance self-efficacy were greater for those participants that ran CST groups. However, the authors did note that the pattern did not necessarily imply causation as they suggested the respondents who ran CST might have enhanced readiness and self-efficacy, as opposed to these characteristics enabling

them to ‘learn’ something. This pilot study justified the measure of learning transfer as well as staff hope as this has been associated with higher QoL for the person with dementia. This study recommended measuring sense of competence as relevant to staff training, CST uptake, and the assessment of CST adherence to evaluate learning. The authors also recommended the evaluation the effectiveness of different training methods, including training versus outreach support, and supervision versus manual only, in addition to assessing QoL and cognition of people with dementia participating in the programme.

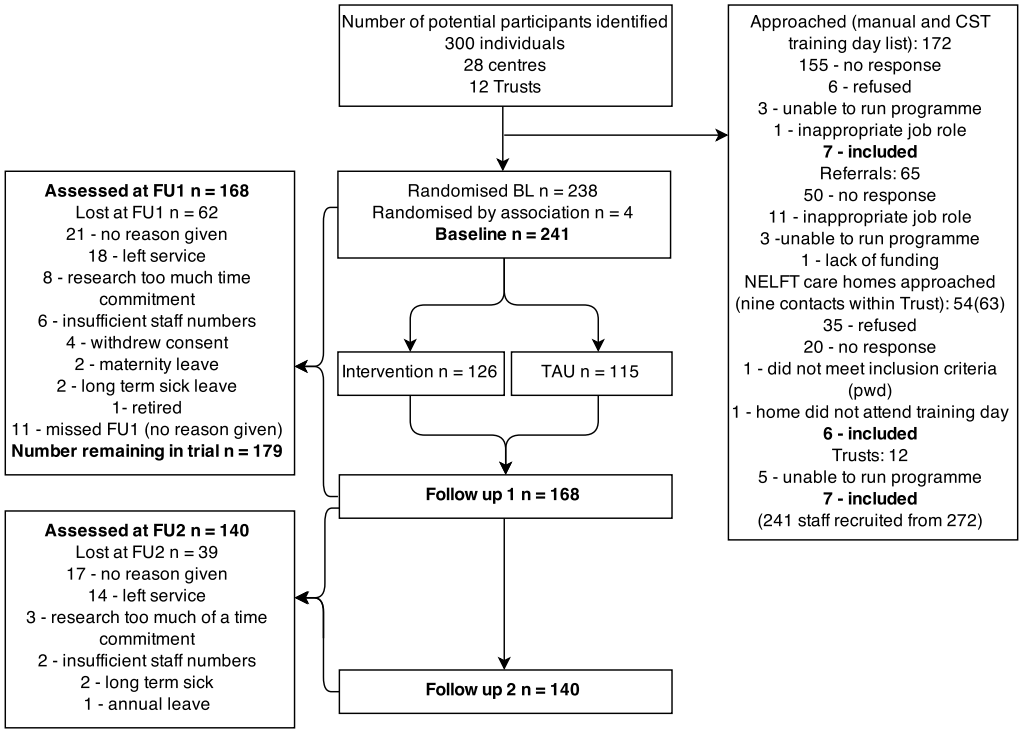
Chapter 5: Results of implementation of maintenance CST in practice: a randomised controlled trial in two streams

5.1 Analysis

5.1.2 Demographics

In total, 300 individuals, 28 centres and 12 Trusts expressed interest or were approached to participate in the research. Overall, 241 staff members were recruited across 63 centres in both the STANDOUT and MONOU studies (Figure 8). 175 staff were recruited as part of the STANDOUT trial and the remaining 66 participants were recruited into the MONOU trial. All the staff members consented and completed the BL assessment prior to randomisation. Four people were randomised by association, after randomisation had occurred but before the centre was aware of whether they were in receipt of the intervention or not.

Figure 5.1: Consort diagram of participants through the STANDOUT & MONOU trials



In total there were 126 (52%) participants in receipt of intervention across 35 centres and 115 (48%) participants not in receipt of the intervention across 28 centres (Table 5.1).

Table 5.1: Breakdown of participant allocation by strand of trial

Trial	**Intervention**	**Number of centres**	**TAU**	**Number of centres**	**Total**
STANDOUT	92	26	83	23	175
MONOU	34	9	32	5	66
Total	126	35	115	28	241

The majority of the staff members' were female (88%) and of white ethnicity (78%), with between one to ten years of experience (43%), and 36% of staff had qualification up to diploma/degree level. Most sites were dementia specialist settings (64%) with 33% being a care home setting (Table 5.2). Job title was also recorded and the occupation most commonly recorded was care staff (33%) (Table 5.3). Both age and ethnic group had missing values, and ASt attempted to collect this information retrospectively, but this was not always possible. The statistician advised randomly assigning missing values based on the percentage reported across the complete dataset, and this was completed for both age and ethnic group. There were 49 missing values for age and these were randomly assigned based on the percentage values across the complete dataset. For the missing data three cells were assigned 18-24, nine cells 25-34, 11 cells 35-44, 14 cells 45-54, and 12 cells as 55+ years. For ethnic group 23 values were missing, and so 18 cells were assigned White (British, Irish, other White background), two cells Asian (British, Indian, Pakistani, Bangladeshi), and one cell Black (British, Caribbean, African, other Black background).

Table 5.2: Participant baseline demographic characteristics

Variable	Category	Intervention	Control	Total
Strand of trial	STANDOUT	93	83	175
	MONOU	33	32	66
Age	18-24 years	8	7	15
	25-34 years	16	28	44
	35-44 years	30	25	55
	45-54 years	42	28	70
	55+ years	30	27	57
Gender	Female	110	102	212
	Male	16	13	29
Ethnicity	White	98	90	188
	Asian	9	8	17
	Black	4	6	10
	Mixed race	0	1	1
	Other	0	3	3
	Did not wish to specify	15	7	22
Experience	< 1 year	5	7	12
	1 ≥ < 10 years	54	49	103
	10 ≥ < 20 years	13	15	28
	20 + years	12	14	26
	Not specified	42	30	72
Type of centre	Care home	36	44	80
	CMHT	32	30	62
	Day Centre	22	9	31
	Day Hospital	18	32	50
	Memory Clinic	3	0	3
	Other	15	0	15
Specialist dementia setting	Yes	73	86	159
	No	53	29	82

Table 5.3: Participants' job titles

Receipt of intervention			
Job title	**Intervention**	**Control**	**Total**
Care Assistant	38	41	79
Occupational Therapist	28	17	45
Manager	8	10	18
Nurse	8	10	18
Healthcare Assistant	2	12	14
Volunteer	9	0	9
Centre Worker	6	0	6
Team Leader	4	2	6
Workshop Leader	0	6	6
Occupational Therapist Technician	2	3	5
Support Worker	4	1	5
Locksmith	3	0	3
Occupational Therapist Assistant	1	2	3
Activities Coordinator	1	1	2
Social Worker	1	1	2
Administrator	0	1	1
Clinical Psychologist	1	0	1
Liaison Psychiatrist	0	1	1
Not specified	9	8	17
		Total	241

5.1.3 Delivery of the CST and maintenance CST programmes

A McNemar's chi square statistic was used to determine the difference in CST and maintenance CST groups run between the intervention and control groups. This method was considered appropriate because it can be used to determine differences between a dichotomous dependent variable with two categories (CST run or not) across two related groups that do not overlap (intervention vs control). For the intervention group 18 (51%) out of 35 centres went on to deliver the CST programme, whereas 12 (43%) out of 28 centres in the TAU group delivered the programme (Table 5.4).

Table 5.4: Number of CST programmes delivered based on intervention

Intervention	**Number of centres**	**No CST n (%)**	**CST programmes run n (%)**
Outreach support	35	17 (49)	18 (51)
No outreach support	28	16 (57)	12 (43)

A McNemar's chi-square statistic suggested no statistically significant difference in the proportion of CST groups run in the intervention group compared to the number of CST groups run in the TAU group (p=.458).

Leading on from the CST programme 12 (67%) of the 18 centres in the intervention group went on to deliver the maintenance CST and eight (67%) of 12 centres in the TAU group delivered the maintenance CST programme (Table 5.5).

Table 5.5: Number of maintenance CST programmes run based on intervention

Intervention	**No CST n (%)**	**CST programmes only n (%)**	**MCST programmes n (%)**
Outreach support n=35	17 (49)	6 (17)	12 (34)
No outreach support n=28	16 (57)	4 (14)	8 (29)

A McNemar's chi-square statistic suggested a statistically significant difference, with more maintenance CST groups run in the intervention group compared to the TAU group (p=.011).

5.1.4 Attendance STANDOUT & MONOU studies

The primary outcome was number of attendees at seven or 14 weeks, and 31 weeks after the initial CST programme dependent on centre

allocation to the treatment group (outreach support) or TAU (no outreach support). This model took into account covariates such as type of centre, delivery of sessions over seven or 14 weeks, whether it is was a specialist dementia setting, and method of recruitment (STANDOUT / MONOU). A combined analysis of the results from the STANDOUT trial (175 participants) and the MONOU trial (66 participants) was carried out. Participants at each centre recorded CST and maintenance CST attendance after each session. The records were collected at the end of the programme and ASt entered these into an Excel spreadsheet. The primary outcome was calculated as the total number of sessions attended for each centre (total number of sessions run x average number of people at each) per centre assuming an intra-cluster correlation of $p<0.05$. For the centres that implemented the programme (30 out of 63) the CST attendance across centres ranged from 42–126 total number of attendees to individual sessions in the programme. In some instances a centre ran more than one programme and this is indicated by the lettering in Table 5.6 (e.g. 1a, 1b, 1c). The total number of individual attendances to the maintenance CST sessions ranged from 30–144.

Table 5.6: Centre attendance for CST and maintenance CST programme

Centre number	CST	Maintenance CST
1a	70	0
1b	70	0
1c	70	0
2	98	144
3	42	0
4	60	0
5a	70	75
5b	70	80
6	56	0
7	70	0
8	42	84
9a	70	144
9b	84	144
10	70	115
11	98	161
12	84	30
13	70	0
14	70	0
15	70	96
16	70	0
17	84	0
18a	84	0
18b	78	0
19	126	128
20	56	110
21	84	144
22	70	115
23	60	0
24a	70	90
24b	84	64
25a	42	51
25b	56	88
26	98	120
27	Missing	96
28	56	96
29	126	120
30	70	96

The primary outcome of total number of sessions attended was calculated for each centre. ASt then grouped the centres to indicate whether CST was being implemented at a low, medium or high level. Centres that did not run the programme scored zero, and delivery of CST at a low level had an attendance score of less than 41, so on average less than three group members in receipt of the programme. Centres with between three to four group members in attendance were considered to have delivered CST at a medium level, and this was reflected in an attendance score between 42-69. If there was on average five or more group members over the duration of the CST programme it was considered that the programme had been implemented to a high level, and this was indicated in a score of 70 or above. Overall, the majority of centres were considered to have run CST at a high level, irrespective of their intervention allocation as demonstrated in Table 5.7.

Table 5.7: Receipt of intervention and rating of CST delivery

Intervention	**No groups n (%)**	**CST low n (%)**	**CST medium n (%)**	**CST high n (%)**	**Total n (%)**
Yes	17 (50)	0 (0)	5 (15)	12 (35)	34 (55)
No	16 (57)	0 (0)	3 (11)	9 (32)	28 (45)
Total	33 (53)	0 (0)	8 (13)	21 (34)	62 (100)

A chi-square suggested no statistical significance between centres in receipt of the intervention and those that were not, and the delivery of the programme, as determined by the average number of attendees across the CST programme (p=0.87 df, 2). However, one centre ran the programme in the intervention group but the attendance and adherence booklet was mislaid, so was omitted from this analysis.

The primary outcome of number of attendees to the programme for the maintenance CST programme enabled ASt to group the centres across the delivery of the extended programme (24 sessions). For no groups run a zero was scored, and less than three group members was indicated by

centres that scored less than 71. Centres with three to four group members scored on average between 71–119 and were considered to have delivered maintenance CST at a medium level. Centres with five or more group members, as demonstrated with a score of more than 120, indicated that maintenance CST had been delivered to a high level (Table 5.8).

Table 5.8: Receipt of intervention and rating of maintenance CST delivery

Intervention	No MCST groups n (%)	MCST low n (%)	MCST medium n (%)	MCST high n (%)	Total n (%)
Yes	22 (63)	2 (6)	5 (14)	6 (17)	35 (56)
No	21 (75)	0 (0)	5 (18)	2 (7)	28 (44)
Total	43 (68)	2 (3)	10 (16)	8 (13)	63 (100)

A chi-square suggested no statistically significant difference between the centres in receipt of the intervention and the average number of attendees in the delivery of the maintenance CST programme (p=0.35 df, 3).

5.1.5 STANDOUT versus MONOU streams

A comparison was also carried out to look at the different pathways that participants entered the trial, either 'new' to CST (STANDOUT) or with previous experience (MONOU). In the STANDOUT trial 17/50 centres went on to deliver the CST programme, and in the MONOU trial 12/13 centres went on to deliver the CST programme (Table 5.9).

Table 5.9: Strand of trial and rating of CST programme

Strand of trial	No CST run n (%)	CST low n (%)	CST medium n (%)	CST high n (%)	Total n (%)
STANDOUT	33 (66)	0 (0)	4 (8)	13 (26)	50 (79)
MONOU	1 (7)	0 (0)	4 (31)	8 (62)	13 (21)
Total	34 (54)	0 (0)	8 (13)	21 (33)	63 (100)

A Chi-square statistic suggested a statistically significant difference with more CST groups run in the MONOU group compared to the number of CST groups run in the STANDOUT group (p=0.001, df 1).

This comparison was also considered for the centres within the two strands of the trial that went on to deliver the maintenance CST programme. In the STANDOUT trial 9/17 centres and 11/13 centres in the MONOU trial went on to deliver the maintenance CST programme (Table 5.10).

Table 5.10: Strand of trial and rating of maintenance CST programme

Strand of trial	No groups run n (%)	MCST low n (%)	MCST medium n (%)	MCST high n (%)	Total n (%)
STANDOUT	41 (82)	1 (2)	4 (8)	4 (8)	50 (79)
MONOU	2 (15)	1 (8)	6 (46)	4 (31)	13 (21)
Total	43 (68)	2 (3)	10 (16)	8 (13)	63 (100)

A Chi-square statistic suggested significantly more maintenance CST groups were run in the centres recruited into the MONOU trial compared to the proportion run in the STANDOUT trial (p=<0.001 df 3).

5.1.6 Use of outreach support

The researcher recorded the amount of times the outreach support options (local supervision, online forum and email support) were accessed by the staff members in the intervention group. Over the duration of the research three contacts were made via email, 15 contacts

through the local supervision option and three participants registered on the online forum. Although three participants registered on the online forum, aside from one query unrelated to CST the service was not used once the participant had registered. For each contact made the query was broken down if more than one issue was raised, in total 25 queries were raised.

The local supervision was originally intended to be a telephone service that the STANDOUT participants in receipt of outreach support could use to contact ASt with any queries. Or, in the instance of the MONOU trial they could use the person they had identified as suitable to provide supervision. However, to document progress ASt carried out monthly FU phone calls with each centre in the STANDOUT and MONOU studies in receipt of the intervention. If a query was raised in this monthly FU phone call it was considered that the participant had used the outreach service.

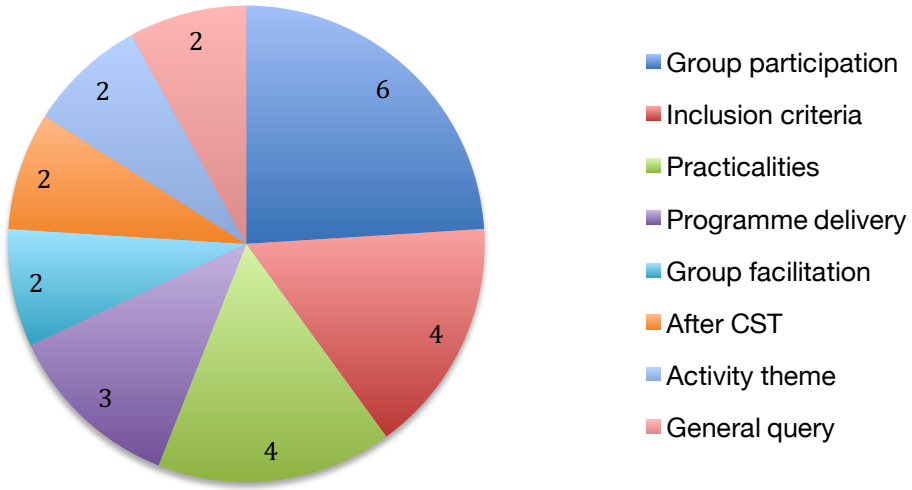
In total, telephone supervision provided by ASt was accessed 15 times, and 19 issues were raised. The participant initiated three of the contacts and ASt initiated the remaining 12 contacts in the monthly FU telephone call. In the MONOU trial three of the Trusts (Kent & Medway NHS Trust, Tees, Esk & Wear Valleys NHS Foundation Trust, & North Staffordshire Combined Healthcare NHS Trust) had clinical supervision already set up and this was accessed in monthly meetings over the duration of their research involvement.

The email support was accessed three times over the duration of the research programme and the participants initiated all three of these contacts. The online forum was signed up to by three participants in the study. However, only one of the participants raised a query on the forum.

The outreach support contact was deconstructed if more than one query was raised. These queries were categorised into eight themes; group

participation, inclusion criteria, practicalities, delivery of the programme, group facilitation, after CST, activity theme, and general queries. Questions related to attendance, group size, and relationships amongst group members came under the theme ‘Group participation’ (n=6). ‘Inclusion criteria’ (n=4) was identified to include questions related to the suitability of group members, such as who should be included in the group. The inclusion criteria tended to be queried in relation as to what to do when the group size became too small. ‘Group facilitation’ (n=2) was used to encompass queries in regards to running the group with low staffing levels. The theme ‘Practicalities’ (n=4) covered issues such as the sourcing of resources and finding a space to run the programme. ‘Programme delivery’ (n=3) included any queries raised in relation to the length / duration of the session or programme, such as the appropriateness of missing a session. Queries related to the appropriateness of an activity came under the theme ‘Activity theme’ (n=2). There were a couple of queries in regards to what to do after the maintenance CST programme, so the theme heading was ‘After CST’ (n=2), and there was also two ‘General queries’ (n=2) in regards to other cognitively stimulating activities available for people with dementia and the identification of an appropriate carer measure (Figure 5.2).

Figure 5.2: Pie chart showing number of outreach support queries raised.



This graph demonstrates the most frequently asked questions related to 'Group participation', with the focus on sufficient group size and the introduction of new group members, understanding the 'Inclusion criteria' and the appropriateness of individuals to participate in the programme, and 'Practicalities' related to room availability and the sourcing of appropriate resources to run the programme.

5.1.7 Delivery of the CST programme

For each CST and maintenance CST session run, the staff members' who delivered the programme were also recorded, in the attendance and adherence booklets. This allowed ASt to determine the number of sessions that the research participants delivered and the amount of additional staff support provided whilst implementing the programme. Across the 241 participants in the STANDOUT and MONOU trials, 101 (42%) participants had some level of involvement in delivering the CST and/or maintenance CST programme. These records were able to demonstrate that recruited participants had attended training and not gone on to deliver the programme. Based on the participants enrolled in

the research the number of staff who delivered the CST programme ranged from zero to three. However, when taking into account all staff members' involved in the delivery of the CST programme this number ranged from one to four staff member's for each session. For the maintenance programme the number of research participants involved in the delivery of the programme ranged from zero to four. However, when all staff members' were included this number ranged from one to six in the delivery of the maintenance CST programme.

Recording this information was useful to explore the number of people required to implement both the CST and maintenance CST programme in practice. Had there not been a record of all staff members involved in the delivery of the programmes there would have been an underestimation as to the number required to implement the programme. This is demonstrated in that there is approximately a one person mean difference recorded between research participants and additional staff that ran both the CST and maintenance CST programmes. So, potentially an additional person has to be factored in to deliver both programmes in practice. Through the use of the records it was possible to identify that in some instances one person per centre ran the programme compared to another centre where there was six staff members' that supported the delivery of the programme. In both the 'Making a difference ' and 'Making a difference 2' manuals the authors advised two facilitators to enable the smooth running of the programme. However, it has been previously identified by the MCST research team (Aguirre et al., 2010) that the programme was frequently only delivered by the researcher, due to unavailability of a staff member and this was identified in the delivery of the programme for this study. The numbers reported in the delivery of the programmes demonstrated the number of facilitators was between one and five. In some instances this created a one to one programme that has not been considered before in a CST group setting.

5.2 Secondary outcome measures

5.2.1 Staff outcome measures

A one-way between-groups analysis of covariance (ANCOVA) was fitted with FU2 as the dependent variable and age, gender, qualification, level of experience, delivery mode (7/14 weeks), type of centre, specialist dementia setting, method of recruitment (STANDOUT/ MONOU) and BL score taken as the independent variables, to compare the effectiveness of outreach support versus TAU. An ANCOVA was considered an appropriate method as there was an experimental and control group with repeated measures (BL, FU1, FU2), and this method controls for the variability in pretest scores (the covariate). So, variance in the dependent variables, such as individual differences were estimated by scores on covariates. By allowing for these adjustments, the covariates can be used as control variables. Out of a total of 241 participants randomised at BL, 115 participants were randomised to the TAU group and 126 participants were randomised to the intervention group (Table 5.11).

Table 5.11: Breakdown of participant allocation by randomised group and number at point of FU

	Baseline	Follow up 1	Follow up 2
Control	115	77	68
Intervention	126	90	72
Total	241	167	140

Based on an intention to treat analysis 140 cases were analysed at FU2 as the primary end point for secondary outcome measures including job satisfaction, approaches to dementia, dementia knowledge, perception of challenging behaviour, perceived sense of competence, and learning characteristics as well as barriers to change taking into account the aforementioned independent variables. Preliminary checks were carried out to ensure that there was no violation of the assumptions of normality, linearity, homogeneity of variances, homogeneity of regression slopes,

and reliable measurement of the covariates. The clinical characteristics of the randomised participants and the mean scores were well matched at BL (Table 5.12).

Table 5.12: Clinical characteristics of randomised participants

Characteristics	Receipt of intervention (n)	Mean (SD)
ADQ score	No (108)	48.7 (5.4)
	Yes (117)	49.9 (4.6)
MSQ score	No (103)	374.4 (49.6)
	Yes (118)	373.7 (52.6)
CBS score	No (114)	53.0 (7.7)
	Yes (123)	54.3 (6.9)
SCIDS score	No (114)	55.4 (7.9)
	Yes (125)	54.5 (7.8)
BLTSI score	No (112)	55.7 (6.7)
	Yes (125)	56.0 (7.1)
BARCQ score	No (111)	35.4 (17.4)
	Yes (123)	34.1 (17.2)
DKQ score	No (115)	3.2 (1.2)
	Yes (126)	3.3 (1.4)

5.2.2 ADQ results

Participants' approaches to dementia was measured using the ADQ that looked at their attitude towards people with dementia, with a low score suggesting a negative attitude and a higher score indicating a more positive attitude (19-95). In the TAU and intervention group the participant score increased slightly at FU1 and FU2. At FU2 the complete data set indicated no significant difference between the two groups, $F_{2, 140} = .60$ $p = .44$, 95% CI [-2.30, 1.30], $d = 0.23$. Table 5.13 demonstrates the adjusted and unadjusted group means, mean differences and standard errors.

Table 5.13: ADQ unadjusted and adjusted scores at FU2 and FU1

		Group	Mean	SE	Mean difference	SE
Follow up 2	Unadjusted	TAU	49.6	0.61	-0.7	0.85
		Intervention	50.3	0.60		
	Adjusted	TAU	49.7	0.64	-0.5	0.92
		Intervention	50.2	0.65		
Follow up 1	Unadjusted	TAU	49.6	0.65	-1.1	0.88
		Intervention	50.7	0.60		
	Adjusted	TAU	49.6	0.60	-1.2	0.89
		Intervention	50.8	0.55		

5.2.3 MSQ results

The MSQ evaluated job satisfaction with a higher score indicating a higher sense of job satisfaction ranging from the lowest score of 100, to the highest score of 500. Both the TAU and intervention groups increased in their self-rated job satisfaction at FU1, but decreased to lower than the mean BL scores for both groups at FU2. At FU2 the complete data set indicated no significant difference between the two groups, $F_{2, 138} = .13$ $p = .72$, 95% CI [-27.25, 18.85], $d = 0.04$. Table 5.14 demonstrates the adjusted and unadjusted group means, mean differences and standard errors.

Table 5.14: MSQ unadjusted and adjusted scores at FU2 and FU1

		Group	Mean	SE	Mean difference	SE
Follow up 2	Unadjusted	TAU	369.9	6.95	3.5	9.67
		Intervention	366.4	6.77		
	Adjusted	TAU	367.6	6.56	-4.2	11.76
		Intervention	371.8	6.99		
Follow up 1	Unadjusted	TAU	381.4	5.82	4.3	7.90
		Intervention	377.1	5.37		
	Adjusted	TAU	375.2	4.46	-5.6	8.16
		Intervention	380.8	4.07		

5.2.4 CBS results

To determine the level of control that a staff member considered the person with dementia to have over his or her own behaviour the CBS was used, with a higher score indicating a higher level of control as rated by the staff member (15-75). The mean score increased at FU1 for both the intervention and TAU groups increased in their mean score at FU1, but decreased in mean score at FU2. At FU2 the complete dataset indicated no significant difference between the two groups, $F_{2, 124} = .37$ $p = .54$, 95% CI [-0.11, 2.71], $d = 0.28$. Table 5.15 demonstrates the adjusted and unadjusted group means, mean differences and standard errors.

Table 5.15: CBS unadjusted and adjusted scores at FU2 and FU1

		Group	Mean	SE	Mean difference	SE
Follow up 2	Unadjusted	TAU	41.7	0.47	0.4	0.64
		Intervention	41.3	0.44		
	Adjusted	TAU	42.1	0.52	1.3	0.72
		Intervention	40.8	0.52		
Follow up 1	Unadjusted	TAU	55.6	0.87	0.8	1.18
		Intervention	54.8	0.80		
	Adjusted	TAU	55.1	0.88	0.1	1.17
		Intervention	55.0	0.80		

5.2.5 SCIDS results

Sense of competence was measured using the SCIDS with a higher score demonstrating a higher perceived rating of competence (17-68). Sense of competence increased for both groups at FU1 and continued to increase at FU2 also. At FU2 the complete dataset indicated no significant difference between the two groups, $F_{2, 136} = 2.17$ $p = .14$, 95% CI [-2.52, 3.12], $d = 0.21$. Table 5.16 demonstrates the adjusted and unadjusted group means, mean differences and standard errors.

Table 5.16: SCIDS unadjusted and adjusted scores at FU2 and FU1

		Group	Mean	SE	Mean difference	SE
Follow up 2	Unadjusted	TAU	59.0	0.92	1.9	1.29
		Intervention	57.1	0.89		
	Adjusted	TAU	58.4	0.74	0.3	1.44
		Intervention	58.1	0.78		
Follow up 1	Unadjusted	TAU	58.9	0.92	2.4	1.27
		Intervention	56.5	0.86		
	Adjusted	TAU	58.0	0.65	0.9	1.27
		Intervention	57.1	0.60		

5.2.6 BLTSI results

To look at training transfer the brief LTSI (Spector, Orrell, Aguirre, 2011) was used including; learning characteristics, motivation, work environment and ability/enabling with a higher score (16-80) indicating a more positive transfer of learning. The TAU group decreased in their mean score at FU1, but increased at FU2. Although not significant the intervention group demonstrated an improvement in their learning transfer between BL and FU1, but this decreased at FU2. At FU2 the complete dataset indicated no significant difference between the two groups, $F_{2, 133}$= 1.05 p = .31, 95% CI [-2.94, 2.94], d = 0.13. Table 5.17 demonstrates the adjusted and unadjusted group means, mean differences and standard errors.

Table 5.17: BLTSI unadjusted and adjusted scores at FU2 and FU1

		Group	Mean	SE	Mean difference	SE
Follow up 2	Unadjusted	TAU	56.5	0.93	1.3	1.31
		Intervention	55.2	0.92		
	Adjusted	TAU	56.6	0.97	0.0	1.50
		Intervention	56.6	1.04		
Follow up 1	Unadjusted	TAU	55.6	0.87	-1.0	1.19
		Intervention	56.6	0.81		
	Adjusted	TAU	55.1	0.76	-2.0	1.21
		Intervention	57.1	0.69		

5.2.7 BARCQ results

Perceived barriers to change including institutional constraints, support from colleagues, philosophical opposition, interference and additional factors, were measured using the BARCQ, with a higher score (0-80) indicating more perceived barriers by staff member. Mean scores for perceived barriers decreased in both groups, but both groups then increased in their mean score at FU2. At FU2 the complete case data indicated no significant difference between the intervention and TAU group, $F_{2, 134}$= .35 p = .56, 95% CI [-4.22, 7.03], d = 0.30. Table 5.18 demonstrates the adjusted and unadjusted group means, mean differences and standard errors.

Table 5.18: BARCQ unadjusted and adjusted scores at FU2 and FU1

		Group	Mean	SE	Mean difference	SE
Follow up 2	Unadjusted	TAU	33.7	1.99	1.6	2.79
		Intervention	32.1	1.96		
	Adjusted	TAU	32.6	1.76	1.4	2.87
		Intervention	31.2	1.92		
Follow up 1	Unadjusted	TAU	29.3	1.50	0.4	2.04
		Intervention	28.9	1.39		
	Adjusted	TAU	29.7	1.43	0.9	2.09
		Intervention	28.8	1.30		

5.2.8 DK-20 results

To understand the staff member's level of dementia knowledge the DK-20 scale was used at BL and FU2 only. Within the scale there are two subdomains including dementia core knowledge and dementia care knowledge with a higher overall score demonstrating a higher level of dementia knowledge (0-20).

Table 5.19: DK-20 unadjusted and adjusted scores at FU2 and FU1

		Group	Mean	SE	Mean difference	SE
Follow up 2	Unadjusted	TAU	2.9	0.25	-0.1	0.35
		Intervention	3.0	0.24		
	Adjusted	TAU	2.8	0.26	-0.6	0.39
		Intervention	3.4	0.27		

At FU2 the complete case data indicated no significant difference between the intervention and TAU group, $F_{2, 136}$= .05 p = .82, 95% CI [-1.36, 1.36], d = 0.30. The adjusted and unadjusted group means, mean differences, and standard errors for DK-20 are demonstrated in Table 5.19.

Overall, the adjusted model of the primary and secondary end points for the secondary outcome measures is demonstrated in Table 5.20.

Table 5.20: Primary and secondary time points for secondary outcome measures: adjusted analysis model

Measure	**Primary end point FU2 (12 months)**				**Secondary end point FU1 (6 months)**			
	Intervention mean (SE)	Control mean (SE)	Group difference. Mean (SE)	Between group difference	Intervention mean (SE)	Control mean (SE)	Group difference. Mean (SE)	Between group difference
ADQ	50.2 (0.65)	49.7 (0.64)	-0.5 (0.92)	F2, 140= .60 *p*=.44	50.8 (0.55)	49.6 (0.60)	-1.2 (0.89)	F1, 167=1.48 *p*=.23
MSQ	371.8 (6.99)	367.6 (6.56)	-4.2 (11.76)	F2, 138= .13 *p*=.72	375.2 (4.46)	380.8 (4.07)	-5.6 (8.16)	F1, 151= .81 *p*=.37
CBS	40.8 (0.52)	42.1 (0.52)	1.3 (0.72)	F2, 124= .37 *p*=.54	55.0 (0.80)	55.1 (0.88)	0.1 (1.17)	F1, 164= .40 *p*=.53
SCIDS	58.1 (0.78)	58.4 (0.74)	0.3 (1.44)	F2, 136=2.17 *p*=.14	57.1 (0.60)	58.0 (0.65)	0.9 (1.27)	F1, 163= .81, *p*=.37
BLTSI	56.6 (1.04)	56.6 (0.97)	0.0 (1.50)	F2, 133=1.05 *p*=.31	57.1 (0.69)	55.1 (0.76)	-2.0 (1.21)	F1, 159=3.51 *p*=.06
BARCQ	31.2 (1.92)	32.6 (1.76)	1.4 (2.87)	F2, 134= .35 *p*=.56	28.8 (1.30)	29.7 (1.43)	0.9 (2.09)	F1, 158= .21 *p*=.65
DK-20	3.4 (0.27)	2.8 (0.26)	-0.6 (0.39)	F2, 136= .05 *p*=.82.				

5.2.9 Adherence and related key principles

The key principle adherence list (Figure 5.3), comprised of 17 questions related to the 18 key principles as described in the maintenance CST 'Making a difference 2' manual. These were collected for each centre that ran the CST and maintenance CST programmes, to determine if the centres that ran the CST programme were adherent to the key principles. A third of the CST adherence records were randomly chosen to monitor the responses given. There were five CST records from both the intervention and TAU centres, including six in the STANDOUT trial and four in the MONOU trial. It was decided to have an even split between the records evaluated in the intervention and TAU group, so as to be able to make a comparison in the reported level of adherence to individual key principles.

Figure 5.3: Key principle related questions

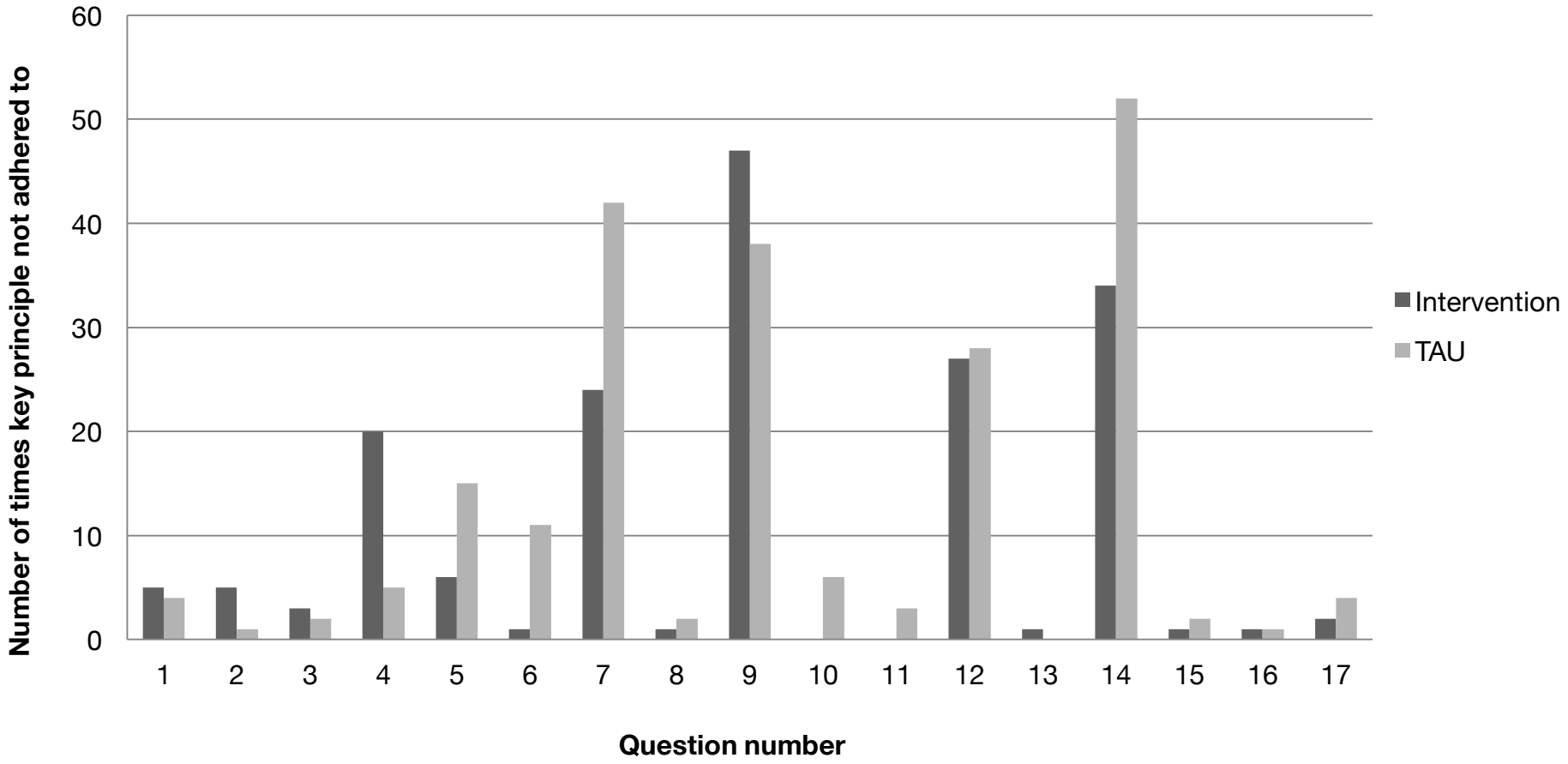
Q.	**Item**
1	Was the session pitched at the right level for all group members?
2	Were people encouraged to think of new ideas during the session?
3	Was time spent on the date, time, weather and feelings of group members?
4	Did the discussion focus on opinion over fact?
5	Were past experiences used to bring people in to the here and now?
6	Did you follow the session structure?
7	Were indirect questions used during the session?
8	Was everyone encouraged to participate in the session?
9	Did anyone struggle to join in with the session?
10	Were the individual needs of each group member met?
11	Was respect shown between group members and the facilitators?
12	Did everyone equally contribute to the session?
13	Was every opinion valued within the group?
14	Were group members given the choice of activities for the session?
15	Did people seem to enjoy the session?
16	Was everyone given enough time to contribute to the session?
17	Is there a good relationship between group members?

Adherence questions left blank or missing were considered incorrect and these were deducted from the overall score that the centre obtained. Self rated non-adherence to the key principle across the delivery of the CST programme ranged from 11-24%. The four main key principle questions not adhered to related to; (7) Were indirect questions used during the session? (9) Did anyone struggle to join in with the session? (12) Did everyone equally contribute to the session? (14) Were group members given the choice of activities for the session? (Figure 5.4). The majority of key principles were evenly matched across the intervention and TAU centres. However, the largest disparities were that the intervention group recorded non-adherence more often to question four (opinions, rather than facts) and nine (stimulating executive functioning), whereas, the TAU group recorded less adherence to question seven (implicit, rather than explicit learning) and question 14 (choice).

When ASt reviewed the responses to the key principles it became apparent that there were two questions that were unclear. Question seven 'Were indirect questions used during the session?' was either left blank, or if answered no, no further explanation was given. This may have been because the facilitator was unsure as to what was being asked, so on reflection this question could include an example of an indirect question to demonstrate the key principle. Alternatively, it might have been more transparent if staff had been asked 'were people asked questions directly or put on the spot?' Key principle nine 'Did anyone struggle to join in the session?' was generally answered 'yes' if there was one person that was deemed more cognitively impaired than the other group members, or if a person was unwell on the day of the session. It was expected that the group member's participation over the timeframe of the programme would vary. Due to this ASt considered this response positive as staff members' were demonstrating their ability to reflect on the running of the session and identify those people struggling during the session. Key principle 12 'Did everyone equally contribute to the session?' was

generally explained in the comments section as a particular group member that required more support, time and prompting than other group members. The programme was designed for people with mild to moderate dementia and so this difficulty was an expected response to this question. For question 14, 'Were group members given the choice of activities for the session?' there was either no comment or it was stated that they were following the session structure as demonstrated in the manual. It was considered that there was a certain level of ambiguity in the question being asked as it was meant to reflect the key principle of choice for group members, as opposed to amending the structure of the programme as a whole, and this may not have been clear in the phrasing of this particular question. All the key principles are important in the delivery of the CST and maintenance CST programme and is one of the reasons CST varies from other psychosocial interventions by providing clear principles to adhere to when implementing the programme. The adherence records were a useful guide to highlight the key principles staff are unsure of and where staff could be more supported to improve the delivery of the programme. In future use of the adherence checklist these question require further clarification to ensure facilitators completing the checklist understand what is being asked.

Figure 5.4: Chart demonstrating staff reported number of times non adherence to key principle question



5.3 Discussion

5.3.1 Recruitment & retention rate

In total, 300 individuals, 28 centres and 12 Trusts expressed interest or were approached to participate in the research. Overall, 241 staff members across 63 centres were recruited into the trial that comprised of 175 staff members as part of the STANDOUT trial and 66 participants recruited into the MONOU trial and at FU2 there were 140 participants remaining in the study. There were two pathways into the trial and for both the STANDOUT and MONOU trial it was possible for staff to nominate themself, management in the Trust / centre could nominate their staff, or ASt approached those that had previously expressed an interest in receiving CST training.

The STANDOUT trial was easier to recruit to as centres were offered the opportunity to receive free CST training by a pioneer of CST ASp, or ASt. As the training costs and materials were free this may have acted as an incentive, and managers wanted to get as many staff members on the training because of this. All Trusts had a PI or LC and this seemed to impact on the organisation within the Trust, as some sites were more familiar with research activity than others. For other clusters, such as the two care home organisations it was harder to conduct the FU monthly telephone call and assessments as the care staff did not tend to have their own individual points of contact, as the manager acted as a 'gatekeeper' to the staff. Subsequently, a lot of time was taken by ASt and the administrator to contact participants in the study.

5.3.2 Measures

At FU time points some staff expressed annoyance at having to complete the questionnaire, as it was considered repetitive, and too long. This was more so the case when staff were not allocated time to complete the questionnaire, and had to find the time in their working day or free time to

do so. It was also difficult for staff to access a computer so paper versions were sent out to participants that required them. In terms of the online questionnaire it had to be completed in one sitting by the participant. However, if it became apparent that a questionnaire was half completed every effort was made to contact the participant and send them the remaining questions so as to not inconvenience them further by making them start the questionnaire again.

5.3.3 Data collection time points

The six month and 12 month FU questionnaire time points were calculated from the point of randomisation. It was explained to participants that the questionnaires should be completed irrespective of whether the CST or maintenance CST programme was being implemented at the time of FU. On occasions this had to be reiterated, as staff did not always think it was necessary for them to complete the questionnaire if they had not been involved in the delivery of the programme. Mid way through the trial it was decided to incentivise staff to complete the final FU questionnaire a £20 Marks & Spencer voucher would be offered as token of thanks. It is unclear as to whether this impacted on the number of completers, but it was considered a small gesture of goodwill due to the time consuming nature of the questionnaire.

5.3.4 Recording the delivery of programme

In total 101 participants recruited across the STANDOUT and MONOU trials delivered all or part of the CST or maintenance CST programme and this was recorded in the attendance and adherence booklets. Had this not occurred there would have been no record of who delivered the programme. Looking through the records it became apparent that some centres used both the CST and maintenance CST programme as a shadowing opportunity for OT students and assistant psychologists, and that there were between one to six facilitators required to deliver the

programme. The published CST manual recommended two group facilitators, but this trial reflects the 'true' number in practice.

5.3.5 Outreach support

The outreach support consisted of online forum, email support and local supervision and was offered to 35 centres and accessed 21 times. As three of these were logging in to the online forum, there were 18 contacts made directly with ASt through the local supervision and email support and from these two avenues of support 25 queries were raised. As expected in the MONOU trial as part of their usual practice three Trusts offered monthly clinical supervision throughout the staffs' participation in the study. Due to this regular access to local supervision, additional supervision offered by ASt may not have been required. The majority of contact (75%) was initiated by ASt as part of the monthly FU telephone call. This increased the number of contacts made with the centres in receipt of outreach support and it should be considered that without the prompt of these telephone calls, this number would be significantly less. Reminders were also sent to centres in receipt of outreach support but this did not increase the uptake of this part of the intervention. The online forum was set up that the participant had to register their details and then be approved by ASt to enter the site. In total the online forum was signed up for by three participants, however only one user raised a query. It might have had a higher user rate had there been a username and password automatically generated for each participant in receipt of outreach support at the beginning of their participation in the trial. An online forum is an interactive site and with no interaction by group members is of limited use. Email support was minimally used and staff verbally told ASt that it was difficult for them to have regular Internet access in the workplace. The general feedback from staff in both parts of the trial was that they were too busy to access any of the outreach support options available to them, and although they could see the

benefit to having them they generally felt that colleagues were able to support one another.

5.4 Conclusion

This trial demonstrated that there is no difference in the level of attendance to the CST or maintenance CST programme irrespective of the centres being in receipt of the intervention. However outreach support appeared to increase the likelihood that the maintenance CST programme would run following on from the CST programme. The MONOU group were overall far better at getting CST and maintenance CST groups running than the STANDOUT group, probably relating to their previous experiences with CST. None of the secondary outcome measures were statistically significant across the TAU and intervention group.

The STANDOUT study was reasonably effective at getting the CST groups operational, with a third of centres going on to run groups. Bearing in mind that the CST training course was only one day, and the numerous examples of training not being delivered in practice this can be seen as a good result. The outreach support intervention was rarely used and the most queries arose as a result of direct contact initiated by ASt rather than by participants. Based on these findings outreach support may not make a difference to getting CST groups running, but may help to support maintenance CST groups in practice. Despite outreach support being hardly used the regular contact by ASt or supervisor within each Trust may have encouraged staff to continue with the delivery of the programme.

Chapter 6: Implementation of maintenance CST in practice: Observational study

6.1 Introduction

This chapter describes the observational study methodology used to carry out an exploratory trial. No previous research has been carried out looking at the delivery of the CST programmes by staff members and the effect this may have on the person with dementia's cognition and QoL when they are in receipt of the programme as part of TAU. Previous CST work has focused on groups delivered as part of research studies, and so this study is useful to determine how far the effects of the CST and maintenance CST programme translate in practice for people with dementia.

6.2 Research question

Are CST and maintenance CST programmes running in practice demonstrating positive outcome measures with people with dementia as shown in previous research studies (Spector et al., 2003; Orrell, Spector, Thorgrimsen, & Woods., 2005; Orrell et al., 2014).

6.3 Aim

In line with phase IV of the MRC framework for the development and evaluation of complex interventions the aim of the observational study was to carry out an exploratory trial evaluating the effectiveness of staff led CST and maintenance CST groups in care settings in practice, in terms of cognition and QoL.

6.4 Hypothesis

Participants' QOL and cognition will improve after attending the CST and maintenance CST programme.

6.5 Ethics approval

This observational study was approved as part of the overall trial by North East London Research Ethics Committee 3, reference number 11/LO/0059 and ethical approval was received for the external sites, including North East London Foundation Trust (Appendix 1.3), Nottinghamshire Healthcare (Appendix 1.6), North Staffordshire Combined Healthcare NHS Trust (Appendix 1.7), Kent and Medway NHS Trust (Appendix 1.8), and South Staffordshire and Shropshire Healthcare NHSFT (Appendix 1.9).

6.6 Site approval

For the observational study the SI or PI for each Trust tended to be the person who made contact with ASt and put their Trust forward as a research site. Once ASt had discussed the purposes of the observational study with the main contact at the site, and it was agreed that they met the inclusion criteria further information was sent to them via email. If after reading the information sheet the person still felt the research was suitable for the Trust they then spoke to the individual managers who would be overseeing the implementation of the CST and maintenance CST programme in the workplace. If managers then agreed that they were able to implement the CST and maintenance CST programme they then approached staff members to decide who would run the sessions. Although, the staff members would not be recruited as part of this study it was important to determine their level of interest in participating in this study before proceeding further. If the staff members' agreed that the study was worthwhile an SSIF was then submitted to the relevant Trust before any further action was taken. When the approval was granted ASt then made contact with the local PI who then asked the managers and staff members to nominate people with dementia who met the inclusion criteria to approach, screen, and recruit into the study.

6.7 Study design and rationale

The observational study was a multi-centre single arm exploratory trial. All people with dementia recruited into the observational study were in receipt of the CST as part of their usual care. Originally the CST programme was designed to be run twice weekly, however it became clear that in practice particular sites were running the programme once weekly as it was considered more manageable. Due to this variation the CST programme was delivered once or twice weekly and the maintenance CST programme was intended to be run once weekly for 24 weeks. Prior to their involvement in the research study no centre had ran the maintenance CST programme as the manual had not been published at the time of the study commencing.

6.8 Sample size rationale

For the observational study a recruitment target of 100 people with dementia was determined taking into account a 15% attrition rate. The attrition rate was an estimation based on previous research conducted in CST (Aguirre et al., 2010). This would give the study a 85% power to detect an effect size of 0.32 at 5% significance.

6.9 Recruitment settings

The recruitment for the observational study took place in 11 centres across five Trusts including North East London Foundation Trust, South Staffordshire & Shropshire Healthcare NHSFT, North Staffordshire Combined Healthcare NHS Trust, Nottinghamshire Healthcare and Kent & Medway NHS Trust. All the managers expressed a commitment to provide support for the staff to run the CST and maintenance CST programme, and allow additional time for staff to complete the necessary screening and assessments with the people with dementia.

Participating centres were identified by either the lead within a Trust approaching ASt, or ASt making contact with a person at a particular

centre or Trust where it was known CST had or was currently running. Once the Trust, or organisation had become enrolled in the trial and the SSIF had been approved people with dementia were recruited in to the trial.

6.10 Sample

6.10.1 Inclusion criteria

To be eligible to participate in the study the people with dementia were required to:

- Have a formal diagnosis of dementia.
- Score mild to moderate on the clinical dementia rating (CDR; Hughes et al., 1982) scale.
- Have adequate spoken and written English.
- Have the ability to participate in a 'meaningful' conversation.
- Have good eyesight and hearing.
- Be able to participate in a group for 45 minutes.
- Be willing to complete the Quality of Life – Alzheimer's Disease (QOL-AD; Logsdon et al., 1999) and Mini Mental State Examination (MMSE; Folstein, Folstein & McHugh., 1975) at three intervals over a year time frame (BL, 7 or 14 weeks and 31 or 38 weeks).
- Not have a major physical illness or disability that could affect their participation in the programme.
- Not have a diagnosis of a learning disability.

6.10.2 Screening people with dementia for eligibility

After obtaining the necessary approval staff within each centre compiled a list of people with dementia that met the inclusion criteria and who had expressed an interest in participating in the programme. A manager, staff member, research nurse, or ASt then approached each individual to discuss the purposes of the research to explain the information sheet (Appendix 3.1) and consent form (Appendix 4.4). The information sheet and consent form was then left with the individual to give them time to

consider their involvement in the study. Each person was then re-approached where any questions were answered and if the person with dementia agreed to participate they were then screened (Appendix 4.3) signed the consent form, and completed the BL assessment outcome measures (Appendix 5.8 & 5.9).

6.10.3 Consent

People with dementia approached to participate in the study were required to be in the mild to moderate stages of dementia and this was determined using the CDR scale (Hughes et al., 1982). Due to this level of functioning it was expected that each individual would be competent to give informed consent for his or her participation in the study. It was made clear to each person with dementia that they were at no disadvantage if they chose not to participate in the research study or decided at a later stage to withdraw their consent. Each individual gave informed consent in accordance with the provisions of the Mental Capacity Act (Department of Health, 2005), and current guidance from the British Psychological Society on evaluation of capacity was followed. The initial giving of informed consent was seen as an indication of preference to participate in the study. However, consent was seen as an on-going process and this was reaffirmed at each assessment time point. If the participant demonstrated any distress during the assessment it was discontinued.

6.11 Measures and data collection procedure

6.11.1 Interview procedure

Interviews with the person with dementia were carried out by a researcher or staff member who was trained to undertake the assessment and had training in Good Clinical Practice and taking informed consent. The assessments were completed in a private area at the centre or care home the participant resided in. Minimal outcome measures on cognition and QoL were collected, using standardised measures with the person with

dementia. At the beginning of each assessment the person conducting the assessment reminded the participant why they were speaking to them, which allowed the person the opportunity to ask any questions. It was generally found that the assessment took between 15 – 20 minutes per person.

6.11.2 Measures for people with dementia

The primary measures of cognition as measured by the MMSE, and QoL as measured by the QOL-AD, were completed at BL and dependent on whether the CST programme was implemented once or twice weekly at seven or 14 weeks for FU1. FU2 was completed after 24 weeks of maintenance CST sessions or after the last maintenance CST session. A level of flexibility was required when considering the time points of the FU assessments as the timing of the delivery of the programme could not always be adhered to for reasons such as lack of staff, lack of group members, or holiday periods.

6.12 Outcome measures

6.12.1 Mini Mental State Examination

The MMSE is considered one of the most widely used rating scales of cognition for people with dementia (Reilly, Challis, Burns, & Hughes., 2004), and is frequently used in clinical practice and research studies. The MMSE is the 'gold standard' of measuring cognition for people with Alzheimer's (Bush, 2007). The measure scores the person's level of orientation to time and place, the registering of three words, attention and calculation, recall, language and visual construction. The scoring of the measure is between 0-30 points, with 0-10 indicating severe impairment, 11-20 moderate impairment, and 21-24 a mild level of impairment. It is expected to take between 15 to 20 minutes to complete with the person with dementia and has demonstrated good reliability and validity (Tombaugh & McIntyre, 1992). Folstein, Folstein and McHugh. (1975) used the measure on a sample of 269 patients with mixed pathology and

established criterion validity, inter-rater and test-retest reliability. Previous studies of twice weekly CST have shown that in general people with an MMSE score between 10–24 have potential to benefit from the programme (Spector et al., 2003; Orrell, Spector, Thorgrimsen, & Woods., 2005).

6.12.2 Quality of Life – Alzheimer's Disease

The persons QoL was measured using the QOL-AD (Logsdon et al., 1999). The QOL-AD is a self-reporting measure on 13-items relating to different aspects of a person's life; physical health, energy, mood, living situation, memory, family, marriage, friends, self as a whole, ability to do chores around the house, ability to do things for fun, money and life as a whole. Each item is rated on a four-point scale ranging from poor (1), fair (2), good (3) and excellent (4). The individual can score between 13 – 52, with a lower score indicating a lower QoL as rated by the person with dementia. The QOL-AD was considered a suitable measure as it was recommended in a consensus on outcome measures to demonstrate sensitivity for psychosocial interventions, to be suitable for people with an MMSE score as low as three, and easy to complete (Moniz Cook et al., 2008).

When asking people to rate these aspects of their life a piece of A4 was printed to assist them in remembering the available choices and also allowed them to answer by pointing if they do not want to verbally respond to the questions. The measure has shown good reliability and validity (Logsdon, Gibbons, McCurry, & Teri., 1999; Thorgrimsen et al., 2003).

6.12.3 Demographic data

A staff member or Ast collected additional information about the person with dementia that included: borough, type of centre, specialist dementia

setting, age, gender, ethnicity, diagnosis and type of dementia, as well as any additional medication.

Chapter 7: Results of implementation of maintenance CST in practice: Observational study

7.1 Introduction

This chapter describes an observational study that recruited people with dementia receiving CST as part of their usual care. The demographic variables at the beginning of the study are shown in Table 7.1. The majority of the sample was female, white and living in the community. The mean age was 80.4 with a SD of 7.2, min=48 max=92. Just over half of the sample had Alzheimer's and just under two thirds of participants were on dementia medication. As most of the participants were living in the community the majority of people accessed the CST programme once weekly through dementia specific day services. Most of the participants had mild dementia with a mean score of 21.2 (SD 4.6) on the MMSE. The majority of the sample also scored in the mid-range on the QOL-AD, with a mean score of 35.7 (SD 7.8).

Table 7.1: Characteristics of observational study

Demographics		**N**
Gender	Female	51
	Male	38
Ethnicity	White	84
	Black	4
	Asian	1
Age	Mean (SD)	80.4 (7.2)
Dementia type	Alzheimer's	46
	Alzheimer's & Vascular	15
	Vascular	14
	Frontotemporal	2
	Lewy body	2
	Unknown	10
Centre Type	Memory clinic	31
	Day hospital	19
	CMHT	18
	Day centre	12
	Care home	9
Specialist dementia setting	Yes	81
	No	8
AChEI's	Yes	55
	No	34
Delivery of CST programme	Once weekly	50
	Twice weekly	36

7.2 Frequency in the delivery of the CST programme

The original CST programme was designed to be run twice weekly for seven weeks. However, this research was run as an observational study with the intention of reflecting what was occurring in practice. Subsequently, for the centres running the programme once weekly this remained unchanged for the purposes of this study (Table 7.2).

Table 7.2: Type of centre and number of participants receiving the CST programme once or twice weekly

Centre type	Once weekly	Twice weekly	Total
Care home	6	0	6
Day Centre	0	12	12
Day Hospital	0	19	19
Memory clinic	26	5	31
CMHT	18	0	18
Total	50	36	86

The people with dementia who attended the CST programme twice weekly and followed this up with the maintenance CST programme immediately after, would receive the programme for 31 weeks. For those people with dementia who received the CST and maintenance CST programme once weekly, the programme would run for 38 weeks. In practice, when the CST programme was delivered twice weekly and followed up by the maintenance CST programme, the length of time participants spent in the study varied between 33 - 39 weeks.

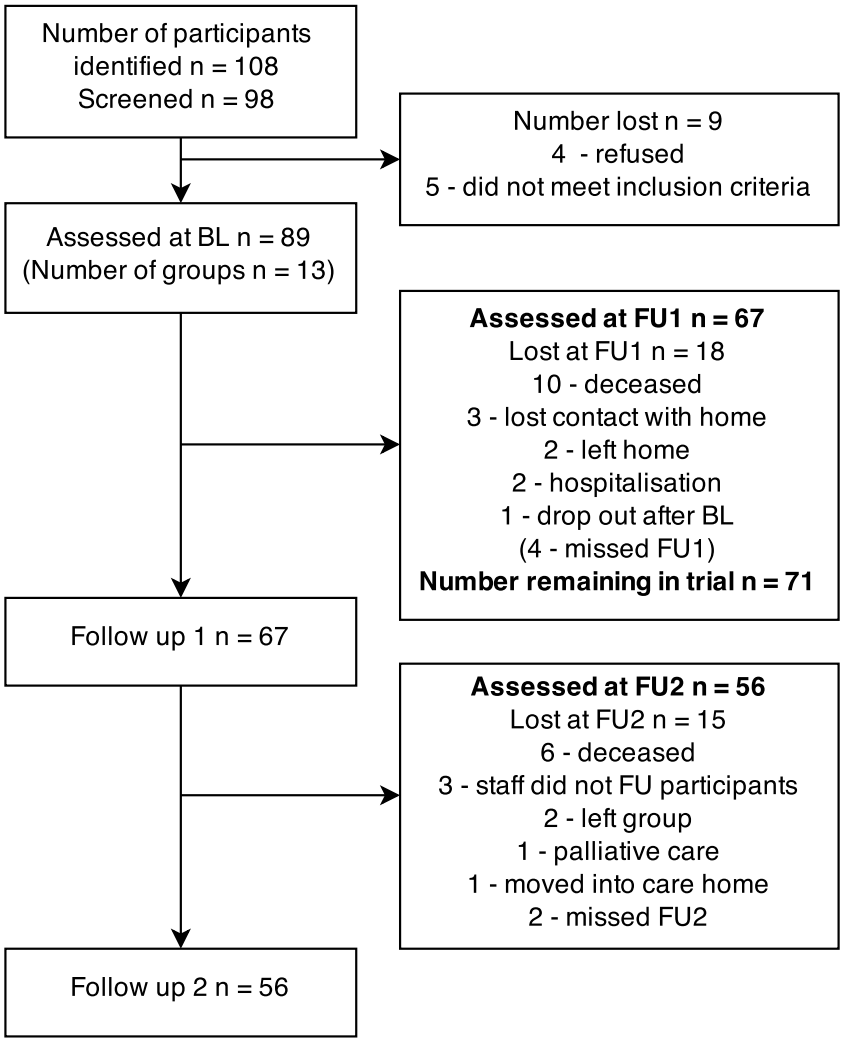
When the CST and maintenance CST programme was delivered once weekly the length of time participants remained in the study ranged from 38 - 56 weeks. Staff members attributed this variation in the delivery of the programme to practical issues such as; time constraints in delivering the programme, staff shortages impacting on the frequency of the delivery of the programme, missing sessions, transport difficulties, public holidays, and lack of group members.

7.3 Retention rate and attrition

The overall retention rate was good. At the primary end point (FU2), excluding death (n=10), there was a 77% (n=56) retention rate. At FU1 (after CST), excluding those that were deceased (n=6), there was an 85%

(n=67) retention rate. The withdrawal rate was similar between both follow up data collection time points (Figure 7.1).

Figure 7.1: Flow diagram of participants through the observational study



7.4 Results

A paired-sample t-test was carried out on the full dataset to determine if the mean time point scores for cognition and QoL between BL and FU1, and BL and FU2, were significantly different from each other. This test was appropriate to determine if the means of two related observations (BL & FU1, BL & FU2) as normally distributed interval variables differ from one another.

7.4.1 Cognition

A paired-sample t-test was conducted to compare mean cognition score at BL and FU1 (after CST). There was no significant difference in the score for BL (M=21.8, SD=4.70) and FU1 (M=21.8, SD=4.88) time point, t(66)=-.98, *p*=.33 or after maintenance CST at the FU2 (M=21.5, SD=5.67) time point, t(55)=-.05, *p*=.96. These results suggested there was no effect on the person with dementia's cognition score over the timeframe of the CST or maintenance CST programmes.

7.4.2 Quality of life

A paired-sample t-test was carried out to compare the mean QoL score at BL and FU1. There was no significant difference in the score for BL (M=36.6, SD=7.32) and FU1 (M=35.7, SD=8.37) time point, t(65)=1.16, *p*=.25. A paired sample t-test was also applied to the mean QoL score for BL and FU2. There was no significant difference in the BL score (M=36.3, SD=7.32) and FU2 score (M=36.7, SD=5.30), t(55)=-.43, *p*=.67. These results suggested there was no effect on the person with dementia's QoL scores over the duration of the CST and maintenance CST programmes.

7.5 Cognitive criteria eligibility to receive the CST programme

However, it became apparent that although all 89 participants were screened and met the specified inclusion criteria, 23 participants scored over 24 on the MMSE. This indicated that not all participants were in the mild to moderate stages of dementia as defined by the MMSE scale (10-24) (Table 7.3). So, in order to meet the inclusion criteria used in previously conducted CST research (Spector et al., 2003; Orrell, Spector, Thorgrimsen, & Woods, 2005, Aguirre et al., 2010, Orrell et al., 2014) these people were excluded from the following analysis.

Table 7.3: Number of participants across centres that scored <25 on the MMSE

Centre type	MMSE scores	Total
Day hospital	28, 27,27, 26, 26, 25, 25, 25	8
Memory clinic	30, 29, 29, 29, 28, 26, 26, 25	8
CMHT	29, 29, 28, 27, 27, 26	6
Day centre	25	1
Total		23

7.5.1 T-test on cognition score for participants scoring 24 or below on the MMSE

A paired-sample t-test was conducted to compare mean cognition score at BL and FU1 (after CST) for people with dementia who scored less than 25 on the MMSE. There was a significant difference in the score for BL (M=19.1, SD=3.48) and FU1 (M=20.1, SD=4.56) time points, t(46)=-2.09, *p*=.04. The same statistical analysis was applied to mean cognition scores at BL and FU2 (after maintenance CST). There was no significant difference in the score for BL (M=19.3, SD=4.05) and FU2 (M=19.6, SD=5.34) time points, t(39)=-.49, *p*=.68. This suggested there was a benefit for people with dementia meeting the inclusion criteria of mild to moderate dementia in cognition, as measured by the MMSE, when in receipt of the CST programme, and was irrespective of the delivery of the programme. Although, not demonstrated to be statistically significant cognition for the person with dementia was maintained over the duration of the maintenance CST programme.

7.5.2 T-test on QoL score for participants scoring 24 or below on the MMSE

A paired-sample t-test was carried out on participants scoring 24 or below on the MMSE to compare the mean QoL score at BL and FU1. There was no significant difference in the score for BL (M=35.7, SD=7.54) and FU1 (M=34.3, SD=9.35) time points, t(45)=1.52, *p*=.14. A paired samples t-test was also applied to the mean QoL score for BL and FU2.

There was no significant difference in the BL score (M=35.3, SD=7.69) and FU2 score (M=36.3, SD=5.64), t(39)=-.89, *p*=.38. Although, there is a one-point improvement over the duration of the CST and maintenance CST programme, this was not considered statistically significant.

7.6 Impact of delivery frequency of CST on outcome measures with the person with dementia

To develop this research further it was considered useful to split the dataset into two groups, of those participants receiving the CST programme once or twice weekly. The analysis was then re-run to determine if there was any difference between the two groups. The results are reported using a mixed model one-way analysis of covariance (ANCOVA) to compare the BL scores to FU1 (after CST) and FU2 (after maintenance CST) time point scores.

7.6.1 ANCOVA analysis on cognition

An ANCOVA was conducted on cognition at both FU1 and FU2. The participants that scored over 24 on the MMSE at BL were excluded from the analysis. In total 47 people with dementia were included in this analysis, 25 participants were included once weekly and 22 participants included as twice weekly. The independent variable of frequency of CST was included as once weekly or twice weekly. The dependent variable was the person with dementia's cognition score at FU1 and the covariates were MMSE BL score, centre type, AChEIs, age and gender. A preliminary analysis evaluating the homogeneity of regression assumption indicated that the relationship between the covariate and the dependent variable did not differ significantly as a function of the independent variable F(1,45)=1.18, *p*=.248. The ANCOVA was significant, F(1,40)=4.44, *p*=.04 (Table 7.4).

Table 7.4: Analysis of covariance for cognition at FU1 by frequency of CST

Source	**df**	**MS**	**F**	***p***
BL MMSE score	1	376.26	39.70	.00
Centre type	1	1.18	.02	.89
AChEIs	1	8.76	.92	.34
Age	1	11.91	1.26	.27
Gender	1	19.40	2.05	.16
Frequency of CST	1	42.05	4.44	.04
Error	40	9.48		
Total	46			

The mean baseline MMSE score was 19.1 and for those participants that received the CST programme once weekly increased by 2.1 points at FU1 to 21.2 (s.e. 6.72). Whereas, the mean MMSE score for participants who received the CST programme twice weekly decreased by 0.2 points to 18.9 (s.e. .73) at FU1. This analysis demonstrated that those in receipt of the CST programme once weekly significantly improved in their cognition score, as rated by the MMSE, compared to those in receipt of the CST programme twice weekly, who remained stable.

Overall, for FU2 40 people with dementia were included in the analysis. The independent variable remained unchanged (CST frequency) and based on number of completers the number of people included, 16 participants in receipt of the CST programme once weekly and 24 participants who received the CST programme twice weekly. The covariates also remained unchanged (MMSE BL score, centre type, AChEIs, age & gender), but the dependent variable was participant's score on cognition at FU2. A preliminary analysis evaluating the homogeneity of regression assumption indicated that the relationship between the covariate and the dependent variable did not differ significantly as a function of the independent variable $F(1,38) = .195$,

p=.66. The ANCOVA did not demonstrate significance F(1,33) = 2.84, *p*=.10 (Table 7.5).

Table 7.5: Analysis of covariance for cognition at FU2 by frequency of CST

Source	**df**	**MS**	**F**	***p***
BL MMSE score	1	471.46	45.72	.00
Centre type	1	1.54	.15	.70
AChEIs	1	1.61	.16	.70
Age	1	5.98	.58	.45
Gender	1	17.39	1.69	.20
Frequency of CST	1	29.24	2.84	.10
Error	33	9.48		
Total	39			

The mean BL MMSE score was 19.3 and this increased by 1.6 points (s.e. .96) to 20.9 at FU2 for those participants receiving CST once weekly. For the participants in receipt of the CST programme twice weekly the mean cognition score decreased by 0.7 points to 18.6 (s.e. .74) at FU2. Although there was a one and a half point increase between BL and FU2 for those participants who received the CST programme once weekly followed by the maintenance CST programme, this was not considered a statistically significant difference. The mean decrease of 0.7 point in cognition for those in receipt of the CST programme twice weekly followed by the maintenance CST programme was not statistically significant. This demonstrated that CST had no significant impact on the person with dementia's cognition score after the delivery of the maintenance CST programme (FU2).

7.6.2 ANCOVA analysis on QoL

The same analysis was applied to those participants that completed the QOL measure. Out of a total of 46 participants, 25 of those people received the CST programme twice weekly and the remaining 21

participants received the CST programme once weekly. The independent variable of frequency of CST was included, once weekly or twice weekly. The dependent variable was the person with dementia's QOL score at FU1 and the covariates were QOL BL score, centre type, AChEIs, age and gender. A preliminary analysis evaluating the homogeneity of regression assumption indicated that the relationship between the covariate and the dependent variable did not differ significantly as a function of the independent variable F(1,44) = .004, *p*=.95. The ANCOVA was not statistically significant F(1,39) = 1.85, *p*=.18 (Table 7.6).

Table 7.6: Analysis of covariance for QOL at FU1 by frequency of CST

Source	**df**	**Mean Square**	**F**	***p***
BL QOL score	1	1993.63	47.50	.00
Centre type	1	17.99	.43	.52
AChEIs	1	13.19	.31	.58
Age	1	12.08	.29	.60
Gender	1	4.10	.10	.76
Frequency of CST	1	77.56	1.85	.18
Error	39	41.97		
Total	46			

The mean BL score for QOL was 35.7 and for those participants in receipt of the CST programme once weekly this increased by .01 to 35.8 (s.e. 1.43) and for those people receiving CST twice weekly decreased by 3.1 points to 32.6 (s.e.1.59). Neither variation in the frequency of the delivery of the CST programme was statistically significant for QOL at FU1.

At FU2 there was a total of 40 participants, 16 people with dementia received the CST programme once weekly and the remaining 24 participants received the programme twice weekly. The independent variable and covariates remained unchanged however the dependent variable was the participants QOL score at FU2. A preliminary analysis evaluating the homogeneity of regression assumption indicated that the

relationship between the covariate and the dependent variable did not differ significantly as a function of the independent variable F(1,38) = 2.06, *p*=.16. The ANCOVA was not significant F(1,33) = .00, *p*=.10 (Table 7.7).

Table 7.7: Analysis of covariance for QOL at FU2 by frequency of CST

Source	**df**	**Mean Square**	**F**	***p***
BL QOL score	1	312.57	12.33	.00
Centre type	1	29.80	1.18	.29
AChEIs	1	63.28	2.50	.12
Age	1	8.44	.33	.57
Gender	1	.60	.02	.88
Frequency of CST	1	.00	.00	.10
Error	33	25.34		
Total	40			

The mean BL QOL score was 35.3 and for those participants in receipt of the programme once weekly this increased by one point to 36.3 (s.e. 1.50) and for those in receipt of the programme twice weekly increased by 0.9 to 36.2 (s.e. 1.16). So, although not statistically significant all participants increased by approximately one point on the QOL-AD by FU2, and this score was unaffected by the delivery frequency of the CST programme.

7.7 Change when comparing to a similar control group

There was no control group for the observational study as CST was considered TAU. However, it was considered useful to compare the cognition and QoL mean change after the delivery of CST in this research study with a similar control group. Independent sample T-tests were used to compare the complete dataset with the control group in receipt of TAU or no treatment in the original CST study (Spector et al., 2003). As there were the same inclusion criteria across both samples it was considered a comparable group. The Spector and colleagues study sample had a

mean age of 84.7 and a 3:1 female:male ratio, whereas the current study had a mean age of 81.3 and a 1.53:1 female:male ratio

Table 7.8: Meta-analysis comparison of mean change in CST groups compared to control group

Measure	**Spector (2003) control Mean change (SD) [N]**	**Current study Mean change (SD) [N]**	**Values**
MMSE	-0.4 (3.5) [70]	1 (4.6) [47]	t=2.04; *p*=0.04
QOL-AD	-0.8 (5.6) [70]	-1.4 (9.3) [46]	t=0.08; *p*=0.94

The participants in the Spector study in receipt of TAU decreased on average by 0.4 points on the MMSE, while the CST group in this study had a mean increase of one point after the CST programme. So, there was a mean difference of 1.4 points (t=2.04 df 115 *p*=0.04) with a confidence interval of 0.07 - 3.52. The MMSE demonstrated a significant increase in the mean score (*p*=0.04) compared to the control group.

In the Spector et al., (2003) study participants decreased on QoL with a mean change of -0.8, whilst the current study decreased on average by -1.4 as measured by the QOL-AD, so there was a mean difference of -0.6 (t=0.08 df 114 *p*=0.94) with a confidence interval of -4.89 to 5.29 (Table 7.8). There was no significant difference in QoL between the control group and the participants in receipt of the CST programme.

7.7.1 Effect size

The mean increase of one point on the MMSE is beneficial when taking into consideration the expected four point annual decrease in cognition for a person with Alzheimer's (Clark et al., 1999). Although, QoL demonstrated no benefit, the significant increase in cognition could be an

economic benefit as demonstrated previously in a research setting (Knapp et al., 2006) when considering CST in practice.

7.8 Discussion

7.8.1 Recruitment & retention rate

Overall 108 people with dementia were approached, 98 people were screened to participate and a total of 89 participants were recruited into the study. So, the study had a high recruitment rate with 91% of people who were approached agreeing to participate in the CST and maintenance CST programme. The four people who refused did not want to commit to the length of the full programme. The overall retention rate was good with a 85% retention rate at FU1 and an 77% retention rate at FU2 (excluding deaths) and the withdrawal rate was similar between both FU data collection time points. The centre staff also made it clear that people could attend the programme and not be in the study, as CST was considered TAU, irrespective of the centres research involvement.

7.8.2 Data collection time points

There was a wide time variation in the collection of the FU data and this should be considered when interpreting the outcome of the analysis on cognition and QoL for the person with dementia. Previously conducted CST research has been standardised in the delivery of the programme and collection of the outcome measures with the BL data being collected a maximum of two weeks prior to the CST programme starting and the FU data collection time points did not exceed the two week timeframe. It should be considered that the length of time taken to deliver the programme in practice, in some instances over a year, might impact on the two outcome measures score. This could not be controlled for due to the nature of the study, but is a limitation when interpreting the results of this study.

7.8.3 Delivery of programme

The expectation prior to commencing the study was that recruited centres would be in the process of setting up or already delivering CST twice weekly, as this was original design of the CST programme. However, it quickly became evident that this frequency was not being followed as some centres expressed that it was considered more manageable to deliver the programme once weekly. As no randomisation occurred centres were able to decide the frequency at which they delivered the CST programme. Consequently, in this study there were 50 people with dementia across six centres receiving the CST programme once weekly and 36 people with dementia across six centres receiving the CST programme twice weekly. Three people were excluded as one centre did not progress pass the BL assessment.

The staff members running the programme were aware of the evidence base for the CST programme yet had not necessarily considered whether these benefits would still be evident with a change in the delivery frequency of the programme. As the purpose of the study was to measure the outcome measures with people with dementia in practice it was decided that centres should continue to deliver the programme as they usually did.

If centres had previously run a maintenance CST programme this tended to follow a similar session structure to the original programme but there was a greater flexibility in the choice of activity, as there appeared to be an opt out mentality to the warm up activities (specifically the group song and ball game), and the programme tended to last between 13-16 weeks. As this varied greatly from the published maintenance CST programme all centres were given the maintenance CST ‘Making a difference 2’ manual and for the purposes of this study asked to run the full programme to ensure that the study was measuring the effect of CST.

7.8.4 Centre type

There was a wide variety in centre type with 89 people with dementia recruited across care home, day centre, day hospital, memory clinic and CMHT settings. Due to the divide in the frequency of delivery of the CST programme across the centres with the day centre, day hospital and a memory clinic running the programme twice weekly and the care home, memory clinic and CMHTs running it once weekly, it would have been useful to examine the differences across these centres further, but due to the small sample size in each centre it was considered that this would be of limited use. The role of the centre could have impacted on the delivery of the programme, as in the care home there is an emphasis on meeting care needs such as washing and toileting, and the delivery of an activities programme is assigned to an activities coordinator, as opposed to the role of care staff. In memory clinics and CMHTs the primary focus is on diagnosis and signposting into other services, with day centres and day hospitals familiar with the provision of daytime activities and programmes.

7.8.5 Frequency in the delivery of the CST programme

Previous small-scale research suggested that the delivery of CST once weekly does not demonstrate any benefit on cognition or QoL for the person with dementia (Cove et al., 2014). However, a difference between this study and previous studies looking at the effect of CST was the mean BL cognition score, with Spector et al. (2003) and Orrell et al. (2014), scoring 14.4 and 16.7, respectively. These mean scores indicated that the participants were generally considered to have a moderate level of cognitive impairment when entering the programme. Similarly, in this study the mean BL cognition score for participants receiving the CST programme once weekly was 19.1, and the mean cognition scored decreased to 18.7 when people not fulfilling the mild to moderate criteria were excluded from the analysis. Both these mean scores indicated a moderate level of cognitive impairment as rated by the MMSE. Whereas,

in the study by Cove et al. (2014) the mean cognition score for the once weekly participants was 22.7, indicating a mild level of cognitive impairment. This could be considered a limitation for this study, as it varies considerably in the mean cognition score compared to previously conducted CST research. The authors identified another limitation as the potential ceiling effect, and so CST becomes less effective. Arguably, further research is required to understand the effect of delivery frequency of the once weekly CST programme as this remains unclear.

7.8.6 Conclusion

This study demonstrated that cognition and QoL was sustained over the timeframe of the CST and maintenance CST programme. However, more emphasis should be placed on meeting the inclusion criteria of mild to moderate dementia, as when the analysis was carried out on the participants that met the inclusion criteria cognition significantly increased.

Importantly, cognition for those in receipt of the CST programme, compared to TAU, was statistically significant between baseline and FU1 (p=0.04). This was an important finding as it is the first piece of CST research directly delivered by staff members' instead of a researcher that has demonstrated benefit in cognition for the person with dementia, and in turn the usefulness of CST in routine practice.

The delivery frequency of once weekly for the CST programme demonstrated benefits for the person with dementia. However, this was not clearly shown for those participants that received the programme twice weekly. Due to the small sample size a further study, preferably an RCT is required to recruit people with dementia that meet the inclusion criteria of mild to moderate dementia to establish this further. However, the CST programme once weekly for 14 weeks, or twice weekly for seven weeks should be strictly adhered to followed by the maintenance CST

programme, to determine if the benefits as demonstrated in previous CST research can be replicated on a larger scale in practice.

Chapter 8: Service evaluation of CST in Redbridge

8. Introduction

In addition to carrying out the observational study North East London Foundation Trust applied for funding from London Borough of Redbridge under Section 256 Health and Social Care Funding to improve dementia services. The assigned funding supported the costs of a CST project manager (ASt) to oversee the implementation of a number of CST related outreach support packages in Redbridge care homes.

The service evaluation aimed to determine if CST training would increase the uptake and delivery of CST and maintenance CST by care home staff, with the additional provision of outreach support. The outreach support consisted of a set up visit, 'spot visits' and telephone support. ASt and Elisa Aguirre (EA) were familiar with CST, and this was considered useful to help the care staff set up the programme, assist if necessary in the delivery of the sessions, as well as provide feedback to improve the delivery of the programme.

This piece of work was considered important to determine the level of support required by care staff to get CST widely disseminated into care settings, in this instance care homes.

8.1 Aim

To carry out a service evaluation and recruit care home staff to train them to deliver CST and maintenance CST, with the additional support of outreach support, to residents with mild to moderate dementia.

8.2 Methods

8.2.1 Training intervention

The standard CST training package was used and ran by ASt. The training was identical to the training delivered in the main research trial (section 2.2.3). Two training days were required to train the number of staff recruited for the service evaluation. After receiving the training each centre was provided with the CST and maintenance CST manuals including the staff training DVD, as well as an attendance and adherence booklet to complete after each completed CST and maintenance CST session.

8.2.2 Inclusion criteria

To be suitable to participate in the service evaluation the staff member was required to be:

- Willing and able to attend a one day CST training day.
- Have adequate understanding of spoken and written English language.
- Able to complete a questionnaire before the training day and at six months.
- Able to set up CST in their care home.
- Working in a care home with over 50% of residents under the responsibility of the London Borough of Redbridge
- Able to identify between five to eight people with mild to moderate dementia willing to participate in the CST and maintenance CST programme.
- Willing to complete an attendance and adherence booklet after each session run.
- Willing to provide qualitative feedback on the effects of the programme.

8.2.3 Sample and data collection

Care homes were identified using the Redbridge Care Directory (2013) detailed as homes catering for people with dementia. Care homes that had less than 10 residents were excluded as it was considered that they were unlikely to have the required number of suitable residents to be in receipt of the CST programme. Overall, 27 care homes were identified as suitable to be approached. Initially each home received a telephone call to explain the purposes of the service evaluation and to determine their level of interest. If the manager requested further information a letter was then sent out to the care home and this was followed up with another telephone call to discuss the project further. If the manager considered the project to be suitable for the home a care home visit was arranged to start the process of identifying suitable residents to ensure they were able to run the programme. Care home managers that agreed to participate in the project identified three staff members who met the inclusion criteria who were able to attend one of two training days. The BL questionnaire was sent to participants or completed by them online before the training day. Forty-eight care staff across 15 care homes attended CST training over two days. However, one person did not complete a BL questionnaire, and another attendee came from a sister home that did not fall under the remit of London Borough of Redbridge, so both people were excluded from the project. In total 46 staff members, across 14 care homes, were included in the project.

No randomisation occurred as the project was considered a service evaluation. Subsequently, all staff members across the care homes received the training day and additional support, to implement the CST and maintenance CST programme.

8.2.4 Measures

The measures completed by each staff member before the training day and at six months included the ADQ (section 4.16.2.3), SCIDS (section 4.16.2.5), brief LTSI (section 4.16.2.6), and DK-20 (section 4.16.2.4).

8.2.5 Ethical approval

As a service evaluation the project did not require ethical approval. However, consent was still obtained from the staff members prior to their study involvement. Before completing the BL questionnaire each staff member signed a consent form to state they had read and understood the information sheet and they consented to participate in the CST service evaluation. Although people with dementia attended the programme no consent was gathered as the programme was considered TAU.

8.2.6 Data analysis

Some participants completed the questionnaires online and the remaining hand completed questionnaires were entered by ASt onto Surveymonkey. Once the FU questionnaires were completed the responses were downloaded into SPSS version 22. Paired sample T-tests were used to compare the outcomes at the two time-points (prior to training and six month FU).

8.3 Results

8.3.1 Demographics

Out of 46 participants, 41 people within the sample were female (89%) and the mean age range was 35-44 years of age (30%). The majority of staff worked in a specialist dementia setting (87%) with a mean range of experience of between three to eight years (39%) and the majority of staff had no formal qualifications (43%), however this was closely followed by an NVQ level of training (41%).

The BL questionnaire was completed by 46 staff members. 23 staff members' completed the ADQ and brief LTSI in full, 29 of the staff members completed the SCIDS, and 10 staff members' completed the DKQ-20 fully. The DKQ-20 had a lower completion rate as many staff either left questions blank or ticked more than one response. Although ASt made attempts to clarify these responses, this was not always possible, and so these participants had to be excluded from the analysis for this particular measure.

8.3.2 Number of programmes run

Of the 14 homes that received CST training, three care homes (21%) attempted to deliver the programme and seven homes (50%) went onto deliver the CST programme in full. Four homes ran the programme twice weekly and three care homes delivered the CST programme once weekly. For the three homes that attempted the CST programme, two homes did not to have enough suitable residents to participate in the programme and the trained staff left the remaining home. Across the seven homes that delivered the CST programme, 55 people with dementia attended the sessions, averaging 7-8 participants per home.

Of the seven homes that successfully completed the CST programme two homes (29%) also completed the maintenance CST programme in the timeframe of the project (nine months from training day), four homes (57%) were midway through the programme and one home (14%) did not run the maintenance CST programme (Table 8.1).

Table 8.1: Number of CST and maintenance CST programmes run in Redbridge care homes

Programme completed	**Number of CST run n (%)**	**Number of maintenance CST run n (%)**
Yes	7(50)	2(29)
Partially completed	3(21)	4(57)
No	4(29)	1(14)

8.3.3 Outreach support

The funding for the service evaluation was for a 12-month period and the training days were organised for three months into this time period. Subsequently the outreach support was offered for nine months, as no support was required prior to this date. The outreach support consisted of set up visits, 'spot visits' and telephone support.

8.3.3.1 Set up visits

Out of the 14 homes, seven (50%) homes required a set up meeting to help identify people with dementia to participate in the programme and two homes dropped out as they felt unable to implement the programme. In total 12 care homes received outreach support over the full nine months.

8.3.3.2 Spot visits

Forty-four spot visits were organised between the researcher (ASt or EA) and the care homes running the intervention. In total each home received between three to four visits. The 'spot visits' included meeting to discuss staff members experiences of running the programme, problem solving, observing the groups in action, and providing feedback to improve the delivery of the programme.

8.3.3.3 Telephone support

In addition to the site visits there were 207 telephone calls made by the researchers to maintain regular support and contact with each home. Each home was contacted approximately 17 times across the nine-month timeframe. Over the service evaluation timeframe email and text contact (16 occasions) was also made available as some staff found it easier to communicate through these channels.

8.4 Results

The paired sample T-test across all measures could only be completed with staff members that completed each of the measures in full at BL and the six month FU. Out of 46 staff members, 15 were unable to complete at the FU time period for the following reasons; dropped out of the project (n=5); did not run the programme (n=3); left the centre (n=2); did not attend training day (n=1); absent at FU (n=1) or no reason was given (n=3). The care staff that completed the measures but missed questions or answered the same question twice were followed up to clarify their answer, but if no response was given these could not be included in the final analysis.

8.4.1 Approaches to dementia

A paired sample T-test was carried out to evaluate care staffs' approaches to dementia prior to training day and at the final FU. There was a statistical difference in the ADQ score from BL (M = 47.83, SD 4.65) to six month final FU (M = 50.70, SD 4.52) t=-2.58, p=.01 (one-tailed) of 23 staff members. The mean increase in the ADQ was 2.87, 95% CI -5.18, -.56. So there was an increase of almost three points in good dementia care practice over the timeframe of the service evaluation, with a larger effect size of 0.62.

8.4.2 Sense of competence

A paired sample T-test to evaluate 29 staff members' perceived sense of competence demonstrated a statistical difference in the SCIDS score from BL (M = 51.17, SD 5.53) to six month FU (M = 59.97, SD 6.50) t=-6.57, *p*=<0.01 (one-tailed). The mean increase in the SCIDS was 8.8, 95% CI -11.53, -6.05. So there was an increase by almost nine points in sense of competence over a six month time period.

8.4.3 Learning transfer

A paired sample T-test to evaluate care home staffs' approach to learning across the timeframe of the service evaluation was carried out. There was no statistical difference in the brief LTSI score from BL (M = 60.26, SD 5.54) to six month FU (M = 61.30, SD 9.64) t=-6.08, *p*=.27 (one-tailed) of 23 participants. The mean increase in the brief LTSI was 1.04, 95% CI -4.60, 2.51.

8.4.4 Dementia knowledge

A paired sample T-test of 10 care staffs' to evaluate dementia knowledge demonstrated no statistical difference in the DK-20 score from BL (M = 4.4, SD 2.07) to final FU (M = 4.6, SD 2.07) t=-.514, *p*=.31 (one-tailed). The mean increase in the DK-20 was 0.2 with a 95% CI -1.08, .68 (Table 8.2).

Table 8.2: Group differences before and after CST using a paired sample T-test

Measure	Time point	n	Mean (SD)	Mean difference (95% CI)	*P* (1-tailed)
ADQ	BL	23	47.83 (4.65)	-2.87 (-5.18, -.56)	0.01
	FU		50.70 (4.52)		
DKQ	BL	10	4.4 (2.07)	-0.2 (-1.08, 0.68)	0.31
	FU		4.6 (2.07)		
SCIDS	BL	29	51.17 (5.53)	-8.80 (-11.53, -6.05)	0.00
	FU		59.97 (6.49)		
BLTSI	BL	23	60.26 (5.54)	-1.04 (-4.60, 2.51)	0.27
	FU		61.30 (9.64)		

8.5 Discussion

This project provided a valuable look at the delivery of CST by care home staff to residents with dementia as part of their usual care. CST is commonly used within a variety of care settings and previous research has indicated a third of attendees after the CST training day go on to run CST in practice (Spector, Orrell, & Aguirre, 2010). However, this project demonstrated that with additional outreach support the uptake of CST increased from 36% to 71%. It also encouraged the uptake of maintenance CST as 86% (6/7) of care homes delivered the maintenance CST programme following on from the original programme.

The spot visits were very well received with staff keen to receive feedback as to their delivery of the programme. The researchers tended to discuss parts of the programme with the care staff member, which they were not so strong in delivering. It was generally found that the planning of the session was not as well thought out, such as the newspaper discussion not being prepared before the start of the session, and this impacted on the running of the session. Another area where the care staff were encouraged to develop their skills was in focussing on implicit rather than explicit questioning, so learning how to ask indirect questions when

running the session. However, overall all care homes were considered competent at delivering the programme and it was unnecessary for the researcher to lead a session. When telephone calls were made to each care home the conversation focused on where the staff member had got to with the programme and any difficulties they had encountered. The main problem was in regards to the sourcing of materials, and the researchers were then able to help with this.

When looking at the cost of delivering CST and the benefit for the person with dementia, CST has been determined as more cost effective than TAU. This service evaluation highlighted the beneficial effects of training care staff and supporting them to implement CST within their care home setting, to improve cognition and QoL for people with dementia, at a minimal cost to the care home.

The positive outcome measure findings were understandable in relation to the intervention. Dementia knowledge was not expected to improve since there was no specific educational course beyond CST itself. Likewise, learning approaches were expected to remain stable over time. However, it is useful to recognise only 10 members of staff fully completed the dementia knowledge measure at the six-month FU. This was generally due to staff answering more than one response and hence their answers were excluded from the analysis. However, the fact that both approaches to dementia and sense of competence improved could indicate that there was an overall improvement in dementia care. Although not necessary for a service evaluation, it might have been useful to have a comparison group of care staff within each of the care homes. This would have been useful to identify if the ADQ and SCIDS score improvements would have been seen across the care home as a whole, or were specific to the staff in receipt of outreach support only.

Having researchers familiar with CST to deliver the outreach support, who were able to reflect on their own experiences was considered sufficient to deal with practical issues that arose within the care homes. There were no instances when the researchers felt inadequately trained to provide the support. The next step may be to have a CST lead that can work across a number of care homes to offer the outreach support that was offered by the researchers.

8.6 Conclusion

The initial attempt at delivering CST was high and remained considerable for staff that successfully ran the full programme. The high rate in the delivery of the programme was also maintained for the maintenance CST programme. This can be attributed to the additional support as delivered by researchers familiar with the set up and delivery of the CST and maintenance CST programme.

CST could be implemented using a fairly minimal amount of outreach support by the researchers. This is a very positive finding and should be examined further to see if this can be replicated on a larger scale. Moreover the positive results in approaches to dementia care and competence suggest that there may be more benefits for care home staff.

Previous research has shown improvements in cognition and QoL for the person with dementia participating in the CST and maintenance CST programme (Spector et al., 2003; Orrell et al., 2005; Orrell et al., 2014). Although not measured in this project it is not unreasonable to assume that these positive benefits for the person with dementia can be replicated in practice as part of their usual care in care home settings.

Chapter 9: Staff focus groups on the delivery of the maintenance CST programme and outreach support

9.1 Introduction

This chapter describes focus groups that were undertaken with staff enrolled in the STANDOUT and MONOU trials and randomised to receive outreach support. Due to the nature of the questions and information sought to guide the development of the maintenance CST programme this qualitative group design was considered the most appropriate 'to explore decision making processes or to enquire about underlying factors' (Britten et al., 1995) as Brown (1999) suggested that the choice of research design should be informed by the design that best answers the research question.

The key objectives were to determine staff members' perception on the delivery of maintenance CST plus the options and use of outreach support as part of the phase IV trial, and this supports the argument to inform implementation and increase participants' involvement in the research process (Lawrence, Fossey, Moniz-Cook, & Murray., 2012). The data gathered from these focus groups was used to inform ASt and other key people related to CST research, in the practical implications of the delivery of the programme, and crucial considerations in the options and delivery of outreach support. The purpose of running focus groups was to provide a more in depth understanding of the group processes and outcomes that in turn could potentially shape the development of the programme further, for maximum uptake within a variety of dementia care settings.

9.2 Methods

9.2.1 Sample

Focus groups were undertaken with staff members enrolled in the STANDOUT and MONOU trial who had completed the CST and maintenance CST programme in their place of work. Not all of the included staff had delivered each session of the CST and maintenance CST programme. However, this did not exclude them from participating in the focus group, as it was felt that they could contribute to the discussion surrounding the implementation of the programme and delivery of the outreach support.

Four focus groups were conducted, one in a care home with three staff members, two with three CMHTs comprising of eight staff members, and one with a voluntary organization of four individuals. In total 15 people, 13 females and two males, participated in the focus groups. 12 people participated in the project as part of the MONOU study and the remaining three people were enrolled as part of the STANDOUT study. All participants had completed their involvement in either strands of the trial. The sample was not ethnically diverse with 97% of the sample being white British. There were also significantly more females than males (97%). However, both of these percentages were to be expected, as both these factors were the majority of the sample in the main trial.

9.2.2 Procedure

When staff members initially enrolled in the study they received an information sheet detailing that the purpose of the focus group was to get a detailed account of their experiences of delivering the programme and experience of outreach support. One of the points they initialled when they consented to enrol in the study was to being approached to participate in a focus group. Verbal permission was also obtained from the manager at each of the centres. An opportunistic sampling method was adopted to recruit staff members who were available, and willing to

participate in the focus group. A £20 Marks & Spencer was given to each person who participated in the focus group as a token of thanks.

9.2.3 Ethical approval

Ethical approval for the focus groups was granted for all sites in the STANDOUT trial when local approval was granted. In terms of the MONOU trial, Kent & Medway NHS Trust granted approval on the 5th of August 2013 after a revision to the protocol to include participants from the MONOU trial. Ethical approval in Kent was obtained, as participants were keen to share their experiences and feedback of delivering the programmes.

9.2.4 Procedure

Individuals were considered eligible if they had previously consented to participating in the focus group and their centre had delivered part of, or the entire maintenance CST programme. There was no distinction made between these two options as it was considered that a centre who had only been able to offer part of the programme could equally contribute to the discussion, as much as staff from a centre where the 24-week maintenance programme had been completed. Arguably, they may be more useful at identifying the barriers to the implementation of the programme, to a centre where the full programme had been completed. This allowed ASt to be as inclusive as possible when recruiting for the focus groups. All staff within centres that agreed to participate in the focus group were approached to take part. This was considered useful to allow the interaction between staff to play out in the focus group, in an attempt to gain a well-rounded perception on the delivery of the maintenance CST programme and addition of outreach support. If this had been limited to particular members of staff (e.g. main facilitators to the group), it may have provided a one sided account of the programme. By being inclusive of all staff it minimised this risk, and the group interaction within centres could be capitalised upon.

Participants were informed of the purposes of the focus group and following on from their written consent, verbal agreement was also sought before being included in the focus groups. Continuing assent was adhered to as each participant was reminded that they were free to leave at any time while the focus group was being conducted.

ASt, LY and PC (BSc student) carried out the hour-long focus groups. ASt and LY had previous experience in facilitating focus groups and had attended courses in conducting focus groups prior to leading and facilitating the groups. The role of the second facilitator was clearly defined prior to commencing the groups. It was established that the role of the second facilitator was to listen and seek clarification, if and when necessary, to ensure accuracy of the content of the groups. The role of the second facilitator was to take substantive notes and record non-verbal interaction amongst group members (Sim, 1998). A semi-structured interview schedule of open-ended questions was used to lead the discussion and was necessary to cue responses to the maintenance CST programme, and outreach support options.

9.2.5 Design

A focus group interview schedule (Appendix 5.10) was developed to create a framework to lead the discussion and both academic supervisors revised this until it was agreed upon. This ensured the questions were well constructed and relevant to the aims of the focus group and to provide a rich data set (Braun & Clark, 2006). A focus group design was considered preferable to individual interviews due to the group nature of CST. This design was suitable in generating discussion and aided in clarifying the participants views that might not be so easily accessible in an individual interview setting (Kitzinger, 1995). The same facilitator led each focus group, which allowed for consistency in the delivery of the interview schedule. Either LY or PC carried out the second facilitator role

and this was dependent on who was available at the time of the running of the focus group. Through open-ended questions participants were encouraged to explore their opinion on the maintenance CST programme, barriers to the implementation of the programme and the delivery of outreach support. The group initially started with a general discussion on the overall perceived positive and negative benefits of the maintenance CST programme and perceived effects on the people with dementia participating in the programme. Questions included 'What do you think are the pro's and con's of the maintenance CST programme?' 'What are the necessary group facilitator skills required to implement the programme?' and 'What was your experience of the outreach support?' The same interview schedule was used across all focus groups.

9.2.6 Analysis

Each focus group was tape-recorded and this was then transcribed. All focus groups were transcribed by Dict8, which is a medical transcription service, to ensure consistency and efficiency in the transcribed data. The person transcribing highlighted any spoken information that was unclear or inaudible on the audiotape, and ASt then reviewed this and clarified the unclear text. To further the interpretation of the transcripts verbal group responses, such as laughter and confirmations amongst group members, were also included. The second facilitator submitted their notes and was on hand to clarify the context in which some comments were made. An inductive (data driven) thematic analysis approach (Boyatzis, 1998) was chosen to code and analyse the data. Inductive analysis is considered a process in which the data can be coded without fitting into a pre-existing coding framework and so is data driven (Braun & Clarke, 2006). This type of analysis was considered the most suitable to gather descriptive exploratory data in relation to staff members perception of the maintenance CST programme and delivery of outreach support.

To develop a thematic codebook ASt familiarised herself with the transcripts and field notes. By creating this familiarity with the text ASt was able to gain a good understanding of the content within the text. Text considered relevant to the aims of the focus groups was extracted and labelled according to their meaning and context in which they were placed. This in turn allowed for categories to emerge from the transcripts (e.g. 'facilitator skills', 'perceived barriers') and the text was then entered under these in an Excel spreadsheet. If an excerpt of text was entered into more than one category, or if there was any level of uncertainty, help was sought from the PhD supervisors. Throughout the analysis process continual comparison and reconsideration of categories was carried out to reaffirm that the generated themes were relevant to the aims of the focus groups.

9.3 Results

The thematic analysis of the focus groups identified the following themes as relevant when considering the maintenance CST programme and outreach support: 'perception of maintenance CST programme'; 'therapeutic value for the service user'; 'perceived barriers'; 'facilitator skills'; 'perception of support'; 'CST adaptations'; and 'quality of materials'. There was a variety of opinions across the themes although generally a natural consensus through the course of answering the question was reached amongst the group members. There tended to be more variation in opinion across, rather than within centres. This difference of opinion was expected and helped in recognising the different difficulties that people encountered when delivering the maintenance CST programme.

9.3.1 Perception of maintenance CST programme

It was generally considered that the maintenance CST programme was not difficult to run. However, staff found it easy to identify the difficulties generated from running an extended CST programme of 24 weeks

following on from the original CST programme. One of the main difficulties was the recruitment and retention of group members throughout the programme.

'It was getting enough people in the first place to actually commit to that length of time' (FG3)

'Because of very low numbers…we felt that this was not good for the people themselves… it is not a good way to spend our time.' (FG2)

'I think it was too long. It's a lot to commit for the staff as well as patients' (FG3)

The difficulty was recognised as the commitment required by service users, as well as the amount of time needed by the staff member to deliver the programme. One of the centres explained their perception of the maintenance CST programme to include considering the implications of not being able to provide the programme to others.

'If we hadn't been doing the long programme we could have got other new people in and through the CST programme thus making the waiting list shorter'. (FG2)

However, a consensus was reached across the groups in recognising that there was a positive response and support from colleagues and family members, who were not directly involved in the running of the programme.

'Their family, the people that brought them in were feeding back on how interactive the person was once they had gone home, how alert they were, how engaging they were… they certainly saw a benefit from them attending'. (FG2)

‘Some staff, they have got a few surprises because sometimes people can make assumptions about service users with dementia and they can still surprise you’. (FG1)

Overall, the participants were able to consider the positives and drawbacks to delivering the maintenance CST programme and the practical implications of offering the full programme in practice. No one disagreed with the design of the programme, or the perceived benefit to the person with dementia.

9.3.2 Therapeutic value for the service user

All participants across the focus groups agreed that there were noticeable improvements in cognition, confidence and well-being for the person with dementia, and that there was a sense of looking forward to attending each session. These benefits were perceived to extend to their wider involvement in the community.

‘More contribution… sense of belonging, belonging an activity, a sense of anticipation and looking forward to it’. (FG1)

‘It’s helped building people’s confidence and motivation to get involved in other community based groups and clubs’. (FG2)

‘One chap said… it’s not often you get the chance to be in a group’. (FG4)

Although, staff members also noted that the therapeutic value could be lost if the group size got too small, or during the delivery of the programme the person deteriorated beyond the group inclusion criteria of mild to moderate impairment.

‘You’re left one day with just two people, it’s not therapeutic, it’s far too intense’. (FG3)

So a negative aspect of the extended programme was the implications of having a longer period of time to maintain the persons level of functioning, group size, and the impact on the group dynamics.

9.3.3 Perceived barriers

A main discussion point of the focus groups was to identify the difficulties experienced by the staff in delivering the programme. The main barriers were split into the following categories; group dynamics, activity choices, staffing levels, transport difficulties, financing the group, and record keeping. It was identified that there was a basic difficulty in keeping people engaged in the activity, and this extended to having people in the group that had deteriorated in their level of functioning. It was felt that this impacted on the running of the overall group.

‘Group work isn’t everybody’s cup of tea’. (FG2)

‘Challenge to engage people’. (FG1)

‘Couple who were started to obviously be more impaired and it was a little tricky to try and keep the thing running when they were obviously struggling’. (FG3)

In addition to the running of the programme it was identified that the group members did not always like particular parts of the structured programme. However, there was no consensus about a particular part of the programme, and it seemed dependent on the particular group in question.

‘Not everyone is interested in (newspaper)… has to be a topic which is pertinent to them that they enjoy talking about and we can engage them in’ (FG1)

‘A lot of them got fed up with the songs, it was oh god not that again’. (FG3)

‘They thought it was a bit childish (ball activity)… you could just tell by body language’. (FG2)

The staff members running the group also highlighted problems in terms of cultural differences between themself and the group members. This also extended to regular availability of the staff required to provide continuity of staff throughout the delivery of the programme.

‘I did make the decision that the leader of the group had to be a person whose first language was English’. (FG1)

The manager made this decision as it was felt the group members struggled in understanding staff when they did not have a proficient level of English to run the group. The manager acknowledged that the staff were excellent carers, but did not have the ability to clearly communicate for the service users to easily understand them. In more general terms it was recognised that staffing levels were low and there was a sense of feeling stretched in their working capacity to deliver the extended programme. The individual difference across the main facilitators as commented on by the service users, was also recognised as a potential barrier.

‘One person who commented on some weeks it was better than others because of who was delivering it’. (FG3)

For the groups taking place in the community a cut in funding required family caregivers to bring their relative. A lack of access to transport and the locality of the group impacted on which service user had access to the CST programme. This was also highlighted as an issue in residential care.

'In residential care I think the main barrier is finance...these are seen as luxuries and so at the bottom of the heap' (FG4)

'The locality, it was transport really, if you can't provide transport for the older person then, unless they've got a really well motivated carer they are not going to get there'. (FG3)

The issue of transport also fed into the difficulty of providing a group that was worthwhile in terms of time for the service user and the family caregiver. The time required to get their relative ready, and the time to get to the session had to balance with the time taken for the session (generally one to two hours).

'If you've got someone bringing their mum in, which has taken them an hour and a half in the car, it could have taken them two hours to get them ready, you know, where is benefit in dropping them off for ninety minutes, there isn't'. (FG3)

This is a pragmatic difficulty that is not directly caused by the programme, but is an indirect factor that can impact on the usefulness and on-going successfulness in the delivery of the programme. A person may start off eager for their relative to participate in the programme but after 24 weeks this initial eagerness might have dwindled due to the effort required to attend the session.

An additional barrier specific to the participants' research involvement was the record keeping of attendance and adherence after each session. The attendance record is located in the CST and maintenance CST manuals, whereas the adherence was created specifically for this project. The staff in the care home found it useful, whereas the staff in the community found it more tedious as they explained they were completing more in depth notes in RiO; an electronic patient record system.

'Laborious. Too time consuming'. (FG3)

Overall, the participants identified many barriers and this appeared to come down to the practical issues associated with the running of a long term programme, alongside other job responsibilities.

9.3.4 Facilitator skills

All of the focus groups reached a consensus that the facilitator skills revolved around being a good communicator, being keen to run the group, familiar with the individual group members and good at managing the group.

'Staff commitment, you need passion really to do it, you need a quiet room and an uninterrupted space'. (FG1)

'You have to be able to observe the group and if someone isn't perhaps participating being able to draw them in and use your skills to encourage them'. (FG2)

'I don't think you use ordinary day to day conversations skills, I think you have to use heartened communication skills… leaving some gaps is really important and I think that the confidence to allow gaps develops over a period of time'. (FG4)

Participants were also aware of the facilitator dynamic when running the group and felt this could impact on the successfulness in the delivery of the programme. It was generally considered that the staff member with more experience would tend to lead the group.

'If you have a good relationship with the person you are working with you tend to be able to run things more smoothly and you are able to discuss afterwards or plan beforehand'. (FG2)

It was emphasised that a good working relationship between facilitators could impact on the planning and reflection of the running of the session.

9.3.5 Perception of support

The general consensus across the focus groups was that the manuals and DVD were sufficient to run the programme but that training was preferable.

'I quite like the idea of training and I think it can't do any harm'. (FG2)

However, it was also recognised that experiential learning was important when learning how to run the maintenance CST programme. Staff also mentioned relying on other colleagues particularly those staff with more experience of those that had attended the commercial CST training day when there were any queries. Many staff did not take up the offer of outreach support for the duration of the research project and this was explained as the manuals being sufficient, and other staff supporting the team.

'Question we had and the support was there and the question was answered so that was the end of it so that was perfectly fine'. (FG1)

‘(Staff name) was our port of call really which is far easier to just go and talk to her’. (FG2)

‘The book gave you enough to follow’. (FG3)

‘There was enough of us to give each other lots of support and learn as we went along’ (FG4)

The outreach support options were rarely used, but participants in the focus group considered themselves to be supported enough by other means for it not to be necessary to access the options available to them.

9.3.6 Quality of materials

The materials required to run each session were considered adequate with staff finding the manuals ‘well laid out, easy to follow’ (FG1).

‘What’s nice about the programme is that you have that element of structure and it’s nice to have that guide of what you’re doing’. (FG2)

However, it was also recognised that not all the suggestions in the manual were useable and on occasion were out of date.

‘Some of these websites as well don’t exist’. (FG2)

‘Couldn’t really use them… we couldn’t reproduce those’. (FG2)

Although, it was also generally accepted by the community settings that their materials were tired and in need of updating. However, this was considered a time consuming task to undertake.

‘It could all do with revamping and again that is another job’. (FG2)

‘Made us realise we could spend some time with some of the team members to try and pull together appropriate resources for each team’. (FG3)

Overall, the manuals for both the CST and maintenance CST programme were sufficient, and the key difficulty identified was a lack of up to date materials to run the programme.

9.3.7 CST adaptations

After having run and provided feedback on the maintenance CST programme as part of a research project, the participants were asked to consider real life adaptations that they felt were useful to deliver the programme. Alterations to the session structure, consideration of a change to the group set up and choice within each session were raised. Choice is a key principle of CST, and the way it was considered by care home staff allowed the service users to pick their own activity.

‘We let the group choose whatever they want to do and we just go with it’. (FG1)

The difficulty with this high level of flexibility of the programme is whether it can still be considered CST. The replacement of one session for another was mentioned due to staff sometimes not feeling confident enough to run the activity for a particular session. Some staff also mentioned that had they not been in research they would have changed the format of the programme more so.

‘We tried to stick rigidly to it as much as possible because it was a research thing… we would have played around a bit more’. (FG3)

Participants reported that they like the structure and the benefits of having something to follow, but on the other hand they also said they

wanted to move parts of the programme around. Again, this called into question when CST becomes an activity session that cannot lay claim to positive measurable outcomes with the service users as demonstrated in CST research.

Within the community setting staff felt it was necessary to add an additional set up and end session, by way of introducing group members and collecting all the information they required to run the programme.

‘We added an extra session at the beginning and the end and we used that for assessment purposes as well and it also kind of breaks the ice’ (FG3)

‘The first group that we do the physical games, we never get around to doing the physical because we really concentrate on the naming the song and vote… so I suppose we are flexible within the programme’. (FG4)

As this left the core programme unaltered it was not considered detrimental to the delivery of the programme. However, the concept of a rolling group was also highlighted as a useful tool in getting people into the service without delay, as they reported an eight-week waiting list, but management ruled this out.

‘Looked at on-rolling group… wouldn’t necessarily be a closed group… were told we couldn’t… because it wasn’t evidence based’. (FG2)

Leading on from this careful consideration of what adaptions to the programme can be made without impacting on the positive outcomes with the people with dementia is required.

9.4 Discussion

The focus groups were an extension of the project to understand the perceptions and perceived barriers to the implementation of the maintenance CST programme, and the lack of uptake of the outreach support options. This was to gain an insight into the practical implications of delivering a long-term intervention in different care settings. It also allowed staff to provide feedback on a programme that they had been involved in for 12 months prior to the running of the focus groups. This was considered important to allow participants to express themselves, and a number of staff members were keen to do this. So an ethical amendment was approved to allow an additional site to contribute to this piece of work.

It was apparent that the staff in the community settings felt they had a high workload and increasing time pressures. It was felt that the maintenance CST programme, leading on from the CST programme, exasperated this as this was above their usual delivery of the programme. However, the perception of CST in the community setting varied from the care home setting. Within the community it was offered as an outreach service, with beneficial outcomes, to start signposting people into other services. Whereas, in a care home it was seen as a programme to be delivered as a regular structured activity programme to the residents. Within the community setting the delivery of CST was considered to be in addition to their usual work role as opposed to something that was factored in to their current workload. This was not something that was mentioned in the care home group setting.

A key limitation in this piece of work is not conducting focus groups with staff members who had not run the maintenance CST programme. This may have been useful, as it may have provided very different perspectives from the staff that participated in the delivery of the full programme. A comparison could then have been made between the two. However, the

main aim of the focus groups was to get the staff perspective of the maintenance CST programme and outreach support and so this would not have been possible had participants been included who had not been involved in the delivery of the programme. Arguably, it would seem likely that the centres that did not run the programme experienced barriers, otherwise it would be expected that they would have run the programme. Although, even for the included centres barriers to the implementation of the programme was the most discussed part of the topic guide, and generated quite a few subthemes. So, despite this limitation staff members that ran the programme were also able to identify the difficulties with the delivery of the programme. Also, although it would have been interesting to recruit staff who did not deliver the programme the information they could provide would only have been limited to the reasons as to why they could not run the programme, as opposed to the programme itself. Additionally, a large number of staff who did not run the programme dropped out during the research, so were not approached to participate in a focus group.

As the purpose of the focus groups was to not only look at perceptions of the maintenance CST programme but the outreach support options also, it was useful to use both centres that had and had not accessed it. Out of the five centres, two centres had accessed one of the outreach support options available to them. So, this was considered a useful split of centres to get a well-rounded understanding of the perception of outreach support. As outreach support was only accessed 21 times across the duration of the research and four of these occasions was the two centres that were in the focus group, it was considered that these centres were able to provide a good account of the use of outreach support.

The external factors affecting the delivery of the programme, such as workload and transport were important to recognise as they specifically

relate to the practical implications in the delivery of the intervention in care settings. To overcome these barriers would be to provide all the materials required for each session, in addition to the manuals already available. The difficulty in doing this is the cost associated with purchasing this. In the same strand transport difficulties could only be resolved by increased funding.

A key factor that kept arising was the alteration of the programme in terms of structure, content, time and order of sessions. A problem with the adaptions of the programme is that the evidence base does not support amendments to the programme. It is necessary to look at this in further detail to see if the service users would still benefit from the programme. Otherwise, the perception may be that CST is being run, when this is not the case.

9.5 Conclusion

The participants considered the maintenance CST programme beneficial for the service users if they still met the inclusion criteria throughout the delivery of the programme, otherwise it was felt there was limited benefit. One of the main concerns was the length of the programme and getting people to commit for a long period of time, as well as ensuring they remained in the programme. Dependent on the purposes of the programme as a signposting service into other services or as a stimulating activity programme could dictate which programme (CST or CST followed by the maintenance CST programme) is most appropriate in dementia care settings. Further research into the potential adaptations made by staff to the programme is required to determine how malleable the programme is, before it does not provide the necessary benefits for the person with dementia.

Chapter 10: Discussion

10.1 Overview

The STANDOUT and MONOU studies demonstrated no significant difference in the delivery of the CST programme irrespective of the addition of outreach support. However, more maintenance CST groups were run for those centres in receipt of outreach support. Building on the main trial the outreach support options were adapted to deliver in care home settings only, and although an alternative study design the Redbridge service evaluation supported the addition of more intensive and local support in the delivery of both the CST and maintenance CST programmes. The addition of focus groups allowed for ASt to obtain a more in-depth understanding in the delivery of the maintenance CST programme and addition of outreach support options from the perspective of the staff members. Practical issues such as the frequency of the CST programme, and length of the delivery of the maintenance CST programme was a key issue, and this was reflected in the length of delivery of the programme in the main trial and observational study. The observational study was key in determining the usefulness in outcome measures for people with dementia receiving the programmes as part of their usual care. When the inclusion criteria was adhered to cognition significantly improved over the duration of the CST programme and cognition and QoL remained stable over both the original and maintenance programmes. All the studies undertaken build up the body of research to support CST, and show a ‘true’ picture of its implementation in practice.

When considering implementation there are various additional sources of support considered useful in assisting in implementation. However, previous evidence is mixed in regards to the effectiveness of staff training. Training has demonstrated it is insufficient to change practice but has also shown an increase in the person centred attitude and job satisfaction of the staff member (Zimmerman et al., 2005). As CST is embedded in PCC

it was considered that the training and additional outreach support could impact on the service delivery and quality of care received by people accessing the various care services. This was not demonstrated in the staff members' primary or secondary outcome measures.
In terms of additional support aside from evidence supporting a multifaceted approach (Grimshaw & Eccles, 2004; Grol & Grimshaw, 2003) there is no sure way to ensure implementation in practice. Due to the mixed evidence the outreach support options for this research study were defined from a survey carried out with CST training day attendees (Spector, Orrell, & Aguirre., 2011). This was a pragmatic approach to defining the outreach support options specific to CST, and overlapped with feedback and reminders as identified in promoting behavioural change amongst healthcare professionals.

This thesis was undertaken as the gap between research and practice is well documented (Grimshaw & Eccles, 2004; Grol et al., 2007), and in relation to CST information in relation to implementation is lacking. In healthcare there is currently numerous frameworks that attempt to compensate for the research into practice gap. However, for the purposes of this thesis the ImpRess scale was specific to cognitive stimulation, with the option of being able to generalise the scale to other cognition based psychosocial interventions.

10.2 Response rate and attrition

10.2.1 Recruitment

The recruitment of staff in to this project was carried out in two different ways, and described throughout the text as the STANDOUT and MONOU studies. The recruitment into the STANDOUT trial was relatively easy, as people had either approached ASp in regards to attending the commercial CST training day, or centres were interested in receiving free training for staff members. At the recruitment stage of the study, the

benefits of CST as the only cognitive psychosocial intervention recommended in the NICE guidelines was particularly useful.

Within the STANDOUT trial there were 'free' elements on offer to centres participating in the research including CST training, the CST 'Making a difference' and maintenance CST 'Making a difference 2' manual as well as the potential benefit of outreach support. All of these 'free' elements provided a useful incentive for staff, centres, managers and organisations to participate in the research project and this was demonstrated through the high level of interest and higher than expected recruitment target. Each centre that participated in the MONOU trial received the maintenance CST manual, and had a 50:50 chance of having the outreach support available to them. For the purposes of the research the participants who had received CST training prior to their research involvement was documented, but no additional training was offered as part of the MONOU study. Fewer incentives for participating in the MONOU study may provide an explanation as to the unequal distribution of staff numbers across the STANDOUT and MONOU studies. However, for the staff that did express their interest in the study they were keen to participate as they enjoyed running the initial programme so were keen to have the opportunity to follow this on with the maintenance CST programme.

There were numerous avenues used to recruit people into the trial, such as using registers of people who had previously purchased the CST manual or attended CST training, DeNDRoN advert as well as being a NIHR portfolio adopted study. Some of the people recruited through the STANDOUT had approached ASp for a training day and then received free training to participate in the programme. This was an incentive for the organisation or manager organising the training to participate in the research, but not necessarily the individual staff member. The additional benefit was the offer of additional support. So, there was the opportunity

to recruit a wide variety of staff from various backgrounds and this was demonstrated in the staff demographics (Table 5.3).

Originally there was intended to be a 50:50 split between staff recruited into the STANDOUT and MONOU trials. However, there ended up being considerably less people in the MONOU trial (n=66) compared to the STANDOUT (n=175) trial. In relation to the MONOU trial there was a degree of uncontrollability as the recruitment targeted a specific type of person (e.g. person with previous knowledge / experience of CST). The initial avenues of recruitment of using registers of people who had purchased the manual or attended CST training, was problematic as the records were vague to begin with. Hawker Publications, as the publication company, kept receipts of the distributed manual, but some of the recorded details referred to an organisation, centre, or administrator, as opposed to the name of the person the manual was being used by. In these instances it might seem unlikely that the correct person would have received the study information sheet. For the CST training day attendance, records were kept as individual training day attendance lists and these had to be collated in an Excel spreadsheet, before people could be contacted. It soon became clear that there were a number of details missing on the attendance registers, such as telephone number or email addresses. Consequently, this created a barrier to contacting all the people that attended previous CST training. Due to these difficulties the pool of potential people to recruit from was small to begin with, and became even smaller after taking these factors into account. For both the STANDOUT and MONOU trials the Trust or organisation had to clearly see the benefits to consider their participation in the study worthwhile as their involvement required the following; investment in time required to recruit staff, time to set up the programme, staff time to run the programme, complete questionnaires, resource materials, identifying suitable group members, and in some cases arrange transportation.

In the observational study the centres were already running the CST programme and it became apparent that some centres were running a 'maintenance' programme beyond CST, but this was not the maintenance CST programme as described in the maintenance CST manual. Centres tended to run a shorter maintenance programme and decide on the sessions themselves rather than adhering to a prescriptive programme. The maintenance CST manual (Aguirre et al., 2011) was provided to each centre to ensure that the programme was being run consistently, and that the outcome measures were measuring the maintenance CST programme instead of a variation of cognitively stimulating programmes.

There were fewer incentives to participating in the observational study staff members, and the centre as a whole, had to see the benefit of recruiting people with dementia to complete the outcome measures over the timeframe of the study. However, this was overcome to a certain degree as centres that were already running or had experience of running CST were approached, so the additional workload was kept to a minimum, in that the extra workload was conducting the person with dementia assessments. Most centres were also keen to conduct assessments to be able to report the benefit of the service users.

10.2.2 Completion of follow up questionnaires

At the time of FU questionnaires, ASt and the administrator reminded centres in the monthly FU telephone call prior to the assessment date. Each participant, or main contact per centre, was sent a reminder email two weeks prior to the estimated completion date. The administrator checked the online survey daily, and the overall database was updated accordingly. A week prior to the completion date another email was circulated as a reminder to the non-completers and another email was sent on the day of the assessment completion date. If the participant had not completed the questionnaire after the email reminders, dependent on

whether the centre was in receipt of outreach support or not, ASt or the administrator conducted a final FU reminder. If the participant did not complete the questionnaire it was entered as a refusal in the database. If a reason was given for non-completion of the questionnaire this was documented in the database, and entered as unable to complete or as a drop out. A difficulty with the questionnaire completion was no face-to-face contact, so ASt relied on people agreeing to complete them in their work hours or in their own time. The difficulty with the survey design was that it required completion in one sitting and this acted as a barrier as people had to block out time to complete the full questionnaire.

It became apparent that there would be a higher dropout rate than had been estimated (Table 10.1) for the sample size to determine an effect size. This occurred in some instances when an entire centre would drop out as opposed to an individual. MO and ASt decided that to thank people for their participation in the study each person would be offered a £20 Marks & Spencer voucher after completing their FU2 questionnaire.

Table 10.1: Breakdown of participant allocation by response rate

Intervention	**Baseline**	**Follow up 1**	**Follow up 2**
No outreach support	115	77	68
Outreach support	126	90	72
Total	241	167	140

At the point of introducing the voucher 142 participants had completed their involvement in the trial and of these participants 81 staff members (57%) completed their final FU prior to the offer of a voucher. For the remaining 99 participants, 57 FU2 questionnaires were completed after the offer of a voucher (58%). So, it was not clear whether the incentive of a voucher had an impact on the number of respondents.

10.3 Methodological considerations

10.3.1 Study design

The STANDOUT and MONOU studies were carried out as a multi-centre RCT and the sample was stratified by centre as a cluster trial design. This was a pragmatic decision to primarily avoid contamination, as staff receiving extra support may run the programme differently, and to ensure that staff from the same centre received the same level of support. This also minimised bias introduced through the potential sharing of information amongst staff members in either strand of the trial. For the purposes of this study cluster randomisation was deemed suitable, as it is considered an appropriate design for evaluating interventions that aim to alter behaviour in healthcare professionals or change organisations or services (Eldridge et al., 2008). Cluster randomisation also measures the effectiveness rather than efficacy, making it internally and externally valid. Although, it can have implications with reduced efficiency and loss of power (Donner, 1998) this was accounted for in the estimated sample size. The similarities between the participants randomised to receive outreach support compared to those that were not offered outreach support were similar. This suggests this design was a suitable way of randomising participants into the trial.

In terms of the ANCOVA statistic there was a large number of covariates. On reflection after looking at the covariate significance there are two covariates (MCST frequency & recruitment type) that could have been excluded from the analysis. Other covariates were important to some of the outcomes, and for the purposes of this analysis a standard model was used. Using a standard model of interest it was expected that not all covariates would be important for the outcomes. In addition level of experience and qualifications were omitted from the analysis, as it was considered that these two outcomes would be irrelevant due to the group nature and environmental factors in the delivery of the programme.

The observational study recruited people with dementia that were receiving CST as TAU, and so no randomisation occurred. The frequency in the delivery of the CST programme was decided within centre and this resulted in more groups ran once weekly in care home, memory clinic and CMHT settings, and twice weekly sessions ran in the day centre, day hospital, and in once instance the memory clinic. This was considered a reflection of what is happening in practice, and is therefore useful to measure any effect that this may have on the person with dementia.

10.3.2 Sample size

The overall recruitment target was powered on the primary outcome of identifying a difference between outreach support or not and impact on attendance to the CST programme. The study was not powered for the secondary outcomes. The secondary outcome measures provide a useful overview of staff perceptions and knowledge before, during and after the research study. The measures also allowed for a comparison between the TAU and intervention group.

The sample size was affected by external factors to the research study such as; restructuring within Trusts so staff moved posts, left current post, retirement, lack of staff time, and lack of suitable participants who met the inclusion criteria and could not commit to the timeframe of the study. There was a higher dropout rate then expected that could partly be attributed to these reasons. However, another reason that became apparent over the duration of the trial was that some participants who had not run the CST or maintenance programme did not feel it was necessary to complete the FU questionnaires, or did not have enough time to complete the questionnaire. On reflection, the staff member questionnaire could have been shortened in an attempt to increase the completion rate. To shorten the questionnaire could have been to omit or use the shortened MSQ, in attempt to achieve a higher retention rate.

For the STANDOUT and MONOU trials the sample size was an overall calculation on numbers from both parts of the trial and calculated based on the number of people in receipt of the intervention. The STANDOUT and MONOU trials combined met and slightly exceeded the recruitment target (241/240). The intention was always to run the analysis on both elements of the trial, so although the aim was to have an equal split, the difference between the two strands of the trial was not considered problematic for the analysis of this trial. Recruitment type was also used as a covariate in the analysis, so an imbalance in this variable was taken into account when the analysis was applied. Sample size was calculated using an effect size for the intervention (outreach support) of 0.4 on number of attendees to the CST and maintenance CST programme with power of 80% using a 5% significance level and an estimated attrition rate of 15%.

The observational study provided an evaluation of CST and maintenance CST in practice on long term cognitive and QoL benefits for the person with dementia. It is the first study to have staff members delivering the CST and maintenance CST programme as TAU, and complete outcome measures with people with dementia. The statistician at N-WORTH calculated that as an exploratory trial 100 people with dementia would be sufficient for the observational study, to determine an effect on the outcome measures, as all participants were in receipt of the CST and maintenance CST programme. Based on 85 participants completing there was an 85% power to detect an effect size of 0.32 at 5% significance. However, at a later stage in the study it became apparent that the delivery of the programme was going to vary considerably, and the sample size could not account for this variation. Due to the small sample size of 86 participants this increased the risk of a Type II error.

10.3.3 Recruitment

As the entire trial was a portfolio adopted study and registered with the DeNDRoN clinical research network it was well advertised from the beginning of the recruitment phase of the trial. There was a high level of Trust interest for both elements of the trial, including staff and people with dementia. Other centres were included that made contact with ASt, or who had approached ASp to receive CST training. This potentially introduced bias at the recruitment stage of the research, as some centres actively pursued ASt to participate in the research project. Also, staff members participating in the MONOU trial had a lesser incentive to enrol in the trial, as they received the maintenance CST manual and 50% chance of being in receipt of outreach support. In comparison staff members in the STANDOUT centres received free CST training, CST and maintenance CST manual, plus a 50% chance of being able to access outreach support. On the one hand, the staff included as part of the STANDOUT trial could have had a genuine interest in running the CST and maintenance CST programme as they made themself available to attend the training day, prior to becoming aware of their potential involvement in the research project. On the other hand, as the training day was offered for free (usually £100 per person) the lead at the site may have included as many people as possible to attend the training day, without fully considering if the staff were able to meet the stipulations of the research project i.e. have time set aside to run the CST and maintenance CST programme. In addition, staff members may have felt an obligation to participate in the research project in order to attend the training day. However, it was made clear that people could attend the training day and not participate in the research programme, but that the Trust would not be reimbursed for these individuals.

At the beginning of the trial managers agreed to allow staff time to run the programme, although there was no way of ensuring this was happening in practice. It may have been useful to create a ‘contract’ with the main

managers and maintain regular contact with them. Yet, the use of a 'contract' may have been of limited use as reasons for not running the programme such as lack of staff or reshuffling within the Trust would not have been overcome by the completion of this.

Some level of difficulty was encountered when recruiting three staff members per centre for the STANDOUT trial. Some centres offered three staff members but on the training day only two people attended. These people were still included in the trial, and where possible a person was randomised by association after the training day. The only requirement was a minimum of three, and in one centre there were eight participants recruited, so there was a wide range in the number of staff recruited per centre. In retrospect it might have been useful to have a maximum requirement as well as a minimum requirement, to keep the centres more evenly balanced in participant numbers.

In some instances it became apparent that the level of understanding in relation to the research process varied across organisations and individuals. When a site had a research nurse or had previous research experience it was generally an easier process with the questionnaire reminders, data collection and collection of paperwork. Although it was clearly explained to participants throughout the trial that the FU questionnaires were completed irrespective of the progress of the CST or maintenance CST programme a common misunderstanding was that when the programme had not begun, or only just started at the time of FU, it was not necessary for them to complete this.

For the STANDOUT and MONOU trials the manager information sheet (Appendix 3.3) that included the staff inclusion criteria was beneficial, in order to give a trial summary and recruit staff members that were suitable to take part in the research project. The screening flowchart (Appendix 4.2) detailing the inclusion criteria for the observational study was useful

to explain to the staff members and managers the inclusion criteria, in order to increase the chances of receiving appropriate referrals for people with dementia that would benefit from the programme. For the observational study there were 23 people with dementia that scored over 24 on the MMSE. When these were excluded from the analysis cognition became statistically significant for those in receipt of the CST programme. Due to this it may have been useful to use the MMSE as a screening tool when identifying suitable participants to participate in the programme.

10.3.4 Receipt of the intervention

The intervention comprised of email supervision, local supervision and online forum. This followed the evidence supporting a multifaceted approach to supporting the implementation of an intervention. There was also the addition of the monthly FU telephone calls for both the intervention and TAU group. This was considered necessary in order to keep up to date records of what stage the centres were at in the delivery of the programme. A common difficulty when completing the monthly FU telephone calls was in trying to get hold of a member of staff participating in the research. The telephone calls were required to start at the beginning of the month, in order to allow enough time in the month to chase up if necessary. In most instances each centre identified a main contact that the administrator or ASt could have regular contact with. If people were not accessing the outreach support options then one member of staff per centre randomised to the intervention group was only having one monthly contact with ASt for the duration of the research. So, there was no way of ensuring that any supervision advice given was filtering down to other staff members in the intervention group.

There was minimal uptake of the outreach support options and this was queried with the participants in receipt of the intervention in the trial. For staff in the MONOU trial it was explained that they already considered

themselves familiar with the programme, so the additional support was unnecessary and any queries that were raised were resolved through peer support. For staff in the STANDOUT trial it was considered that the training day and both manuals were comprehensive enough to not require the additional support. Anecdotal feedback provided by staff members in the intervention group also highlighted that the monthly FU telephone call provided an opportunity to ask questions, as opposed to chasing it up themself, and in addition it was considered low on the list of priorities in terms of workload. However, the regular monitoring could have made the centres more vigilant. The lack of uptake of outreach support options may also be partly explained in some instances due to a lack of uptake of the CST and maintenance CST programme, as in those instances the outreach support is of limited use.

10.4 Instruments

10.4.1 Rationale for selection

For the STANDOUT and MONOU trials the primary outcome was number of attendees to the CST and maintenance CST programme. This was chosen as the main outcome as it was the considered the most logical way to look at the impact that outreach support may have on staff when implementing the programme (e.g. with outreach support the staff are more likely to run the programme, in turn increasing the number of attendees to the programme).

The staff measures were used as secondary outcome measures. Consequently, the study was not powered on these outcomes to detect an effect size, so were always intended to be hypothesis generating rather hypothesis confirming. To provide a useful picture of staff demographics the measures were chosen across dementia knowledge, competence, job satisfaction, challenging behaviour, approaches to dementia, perceived barriers to change and learning transfer to determine if these fitted within the general care population.

Considering the BL scores the participants were well matched across the TAU and intervention groups. In the pilot study of the uptake of CST after one day training (Spector, Orrell, & Aguirre, 2011) learning transfer, job satisfaction, and attitude towards dementia was measured. An independent T-test compared respondents that had taken up CST to those that had not. The respondents that implemented CST scored higher on the brief LTSI on ability / enabling and work environment, whereas job satisfaction and attitudes towards dementia remained unchanged across the two groups. The authors concluded that those attendees who went on to run CST demonstrated better learning characteristics than those that did not. As this was a small study it was considered useful to use these measures on a larger scale to determine if there was any change between those that received outreach support and those that did not. In addition it was considered useful to look at competence as one might expect that if staff were able to deliver the CST and maintenance CST programme and receive on-going support to implement the programme they might increase in their perceived level of competence, as measured by the SCIDS. This provided a rationale for these particular measures used in the trial.

In terms of challenging behaviour the CBS was a useful measure to use with participants to determine how responsible the person with dementia is perceived to be for their actions, when presenting with challenging behaviour. As CST takes a person centred approach the participant's perspective may change over the duration of the programme. Similarly, barriers to change aimed to identify opposition, level of support, dissatisfaction and interference. This might alter over the timeframe of the research programme with the addition of the outreach support, as one of the purposes of the support was to assist in problem solving for the staff within the centres. Dementia knowledge used prior to randomisation and at FU2 was a useful measure to determine change over time. Adherence

as measured by the key principles checklist was also considered useful to identify whether the programme was being adhered to, and whether there were common difficulties that could inform the future development of CST. There was variation in the reporting of adherence across the intervention and control group. Those in receipt of outreach support highlighted difficulty in adhering to focussing on opinions, rather than facts and stimulating executive functioning. Whereas, the control group had difficulty in carrying out implicit, rather than explicit learning, and giving choice to the group members. On further examination of the responses given some centres misinterpreted the question being asked. Although, a key aim of the adherence checklist was to keep it short and manageable for the group facilitators. On reflection further detail may have been useful to provide guidance when completing the questions on the adherence checklist.

In relation to the observational study the primary outcomes of cognition and QoL were considered the most appropriate measures as they have both been consistently used in research relating to the delivery of CST, and so this allowed a direct comparison with previous research. In some instances staff were completing the outcome measures with the person with dementia, so it was also necessary to choose measures that were short and easy to complete, so as not to overwhelm the staff member or the person with dementia. The QOL-AD is also recommended for research and clinical practice (Moniz Cook, 2008) and for people with Alzheimer's the MMSE is the 'gold standard' to measure cognition (Bush, 2007).

A benefit for staff completing the measures with the person with dementia is that they have already had the opportunity to build up a rapport with the person over the CST and maintenance CST programme. This may have introduced a bias as staff members were aware that the person was participating in the programme, and also the expected benefits that one

might expect to see from participating in the programme. However, as there was no TAU group for the observational study this potential bias could occur irrespective of who completed the outcome measures with the person with dementia. It was reiterated by ASt that people could take breaks when necessary, but this rarely happened, as the questionnaire was relatively short, taking between 15 - 20 minutes to complete. All the measures across the STANDOUT and MONOU trial and the observational study were considered to have adequate internal reliability and validity to be suitable for the target population in this research project.

10.4.2 Limitation and issues in use

The questionnaire was completed by researchers prior to the recruitment of centres to determine the length of time required, and it was estimated to take 30-40 minutes. However, the length of time required to complete the questionnaire was the main issue raised in the STANDOUT and MONOU trials. In practice participants reported the questionnaire taking up to an hour, and this was considered too time consuming, so to overcome this the number of measures could have been reduced. On consideration the short form job satisfaction questionnaire and dementia knowledge measure could have been omitted as both were unlikely to provide useful information in relation to understanding the implementation of the full programme. To reduce the number of measures may have encouraged the completion of the questionnaire at each time point, particularly for staff members who were not running the programme. However, ultimately the completion of the questionnaire got quicker at each time point as the participant became familiar with the questions being asked. Yet a certain level of frustration was expressed by some participants, in regards to the repetitiveness of the measures. Another issue raised was that some participants felt that not all questions were relevant to them, so were difficult to answer. This was in particular reference to the brief LTSI that was completed prior to the CST training day. As the measure focused on how training relates to work practice,

some participants felt they could not answer this accurately prior to the training. In retrospect it would have been more useful to ask participants to complete this particular measure post training, to get a truer reflection of how they perceived themself to implement the training in their care setting.

10.4.3 Experiences of use

In the observational study there were occasions where participants answered QoL as it was, as opposed to how it is now. Although, the interviewer did attempt to bring the person with dementia back to the present and ask them to respond to how they are currently feeling, this did not always happen. It was also reported by some staff that they were not sure that the person with dementia fully understood what was being asked of them. The QOL-AD has been identified as being suitable for people with a higher level of impairment, as rated by the MMSE (Hoe et al., 2005). Therefore, the difficulty in responding may have been how the question was being asked by the interviewer, as opposed to a problem with the questions in the measure.

The participant questionnaires in the STANDOUT and MONOU trial were intended to be completed, via Surveymonkey. This was considered a suitable online tool to run a National study and collect the responses in a timely manner, as well as reduce the risk of error at the stage of inputting the data. However, in some instances staff were sent paper versions of the questionnaire and these were then returned to ASt and hand entered into Surveymonkey. For the hand completed questionnaires there was a tendency, particularly with the dementia knowledge questionnaire, to circle more than one response. This tended to be the case when the participant was unsure how to answer, and this could have been avoided if the questionnaire had been completed face to face with a researcher. However, this was not possible, as ASt worked independently on the research project, and also the FU time constraints did not allow for this.

10.4.4 Data collection

Despite management and participants agreeing at the time of recruitment, and signing the consent form, to allow time to complete the FU questionnaire, there were frequent delays in the completion of this. The level of commitment to completing the questionnaire varied between participants, and there were occasions where managers and staff were feeding back at FU time points that they did not understand the reasoning for completing the questionnaire if they had not been running the programme. Some managers were supportive and encouraged staff to take time to complete the questionnaires, whereas others considered their workload to be too high already.

On occasion participants verbalised that there was too much paperwork to complete, when taking into account the attendance and adherence records required for the research project. This was expressed particularly in Trust settings where information was already being entered onto RiO. As there was already a record keeping system, participants felt that at times work was being duplicated, and that overall it was too time consuming. In retrospect, it may have been useful for ASt to carry out random adherence checks. Although, these checks would have been more time consuming for ASt it would have provided a more objective measure of whether the group was adhering to the adherence checklist. However, had this occurred it might have been difficult for ASt to remain uninvolved in issues that the staff were experiencing when running the group, and in doing so provide support on the day for the TAU centres.

10.5 Internal validity

10.5.1 Selection bias

Using a remote randomisation unit, NWORTH, reduced the selection bias. Clusters of staff were assigned a number (1 or 2) per centre by an administrator and this was then sent to NWORTH who conducted the randomisation and allocated the clusters to receive the intervention or

not. The two groups were well matched at BL suggesting that this was a well chosen study design to reduce selection bias. However, there was an occasion when ASt became unblinded, as the administrator sent the randomisation result with the centre number that correlated to the participant identification numbers. The support for this research trial was administration only. It may have been possible to reduce this risk of error from occurring by recruiting a research assistant to carry out the randomisation process.

10.5.2 Performance bias

For the training days performance bias was kept to a minimum by having two CST trainers (ASp & ASt). Attendees also completed evaluation forms after each training day in an attempt to manage any discrepancies between the two trainers. However, on a Likert rating scale with 1 = poor and 5 = excellent, feedback across the training days was similar for both trainers (Table 10.2).

Table 10.2: Comparison of CST trainer feedback

Question	**Trainer A**	**Trainer B**
CST knowledge before training	3.0	2.5
CST knowledge after training	4.3	4.1
Trainer style of presenting and facilitation	4.2	4.4
Trainers ability to answer questions and approachability	4.4	4.6
Trainers knowledge about the subject	4.5	4.7
Pacing of sessions	4.1	4.1
Balance between theory and practical	4.0	4.1
Opportunity to discuss learning and relevance to work	4.3	4.3
Opportunity for me to participate was	4.2	4.4
Satisfaction with training day	4.3	4.5

Both ASp and ASt were required to deliver the training due to the number of staff recruited for the STANDOUT trial. As the feedback was similar across trainers, the efforts to train ASt were considered sufficient for the purposes of the training.

In the STANDOUT and MONOU trials participants could not be blinded to whether they were in receipt of the intervention or not. As participants were aware of the randomisation result this could have led to 'resentful demoralisation' (Medical Research Council, 2000) for those in the TAU group, and affected the responses given.

In order to assess compliance with the programme an adherence checklist was developed specifically for the research trial, and participants were asked to complete this after each CST and maintenance CST session. This was to ensure that the programme was delivered as intended as per the 'Making a difference' and 'Making a difference 2' manuals, and followed the key principles of the programme. This provided a comparison to be made between those receiving the intervention delivering and not delivering the programme, as well as those recruited as part of the STANDOUT trial compared to those in the MONOU trial. Comparing the two strands of the trial there was not too much dissimilarity across both groups, indicating that the similarities were apparent regardless of level of CST experience.

The facilitator delivering the programme to the person with dementia varied across and between centres in the observational study. This may have impacted on the delivery of the programme and staff reported incidences where participants favoured particular staff to lead the session. There was also a number of staff, as well as ASt, completing the BL and FU questionnaires with the person with dementia. It may have been useful to have the same person (ASt) completing the questionnaire at each time points with the people with dementia from each site.

However, for logistical reasons and time constraints it was not possible for ASt to complete all of these.

10.5.3 Attrition bias

There appeared to be no attrition bias, as the overall attrition rate did not vary much between the intervention and TAU groups (Table 5.11).

10.5.4 Detection bias

It was not possible to keep the managers and staff members blinded to the randomisation allocation, and so this may have altered the responses given at FU. As previously mentioned participants varied in how they completed the questionnaire, and this impacted on the quality of the data collected. However, this bias could be applied across all centres and participants.

The researcher made every concerted effort to remain blinded throughout the research process, however on occasions this was not always possible. This occurred if participants revealed their identification number when attempting to access the online questionnaire. To keep ASt blinded to allocation of randomisation, participants were reminded to contact an administrator for their identification number, but this did not always happen. However, as questionnaires were completed independently of the researcher, this was considered unlikely to have impacted on the responses given.

10.5.5 Reporting bias

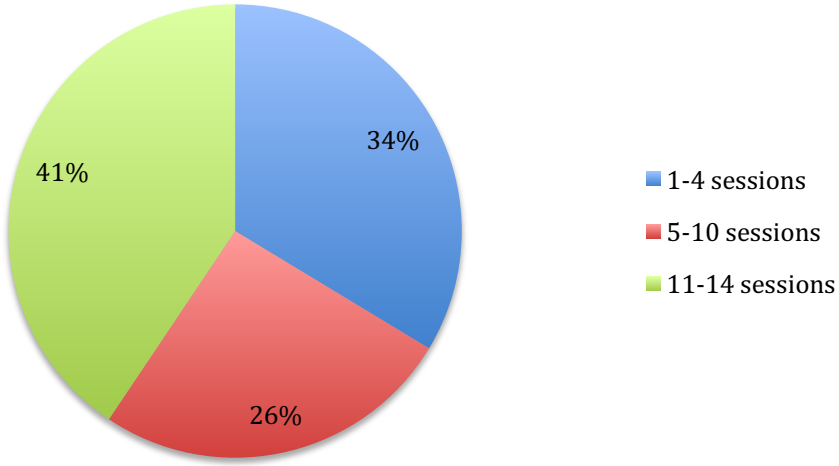
The analysis for both the STANDOUT and MONOU trials and observational study were conducted in accordance with previously defined data analysis plans (Appendix 22 & 23) to prevent data dredging. All reported data within this thesis and further dissemination of maintenance CST implementation in practice has adhered to, and will continue to adhere to these analysis plans.

10.5.6 Group compliance

Across the 63 centres, 30 CST programmes and 20 maintenance CST programmes were completed. The number of sessions required to be run by a staff member was never specified, and so this varied considerably from no sessions to the full 14 CST sessions offered by one member of staff (Figure 10.1). This was also the same for the maintenance CST programme, with some staff members having no involvement in the running of the programme, and other staff members delivering the full 24-week programme (Figure 10.2). This variation was recorded, but could not be controlled for. This level of variation in the length and frequency delivery of the programmes is not wholly unexpected and the difficulties demonstrated in this study are supported in the identified barriers to staff implementing nonpharmacological interventions in care home settings (Lawrence, Fossey, Moniz-Cook, & Murray., 2012). A difficulty arises when one considers who is responsible for the initiation and delivery of interventions in care settings.

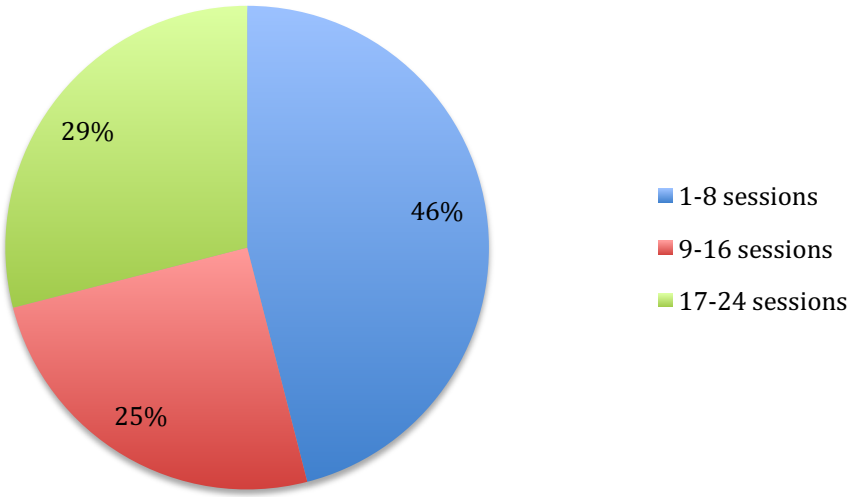
In total 101 participants assisted in the running of the CST programme with 34% of participants having some level of involvement in 1-4 sessions, 26% of participants delivering between 5-10 sessions and 41% of participants delivering between 11-14 sessions. So the majority of participants that ran the CST programme delivered a high number of sessions. However, two centres ran an 11 session CST programme, and one centre ran a 13 session CST programme.

Figure 10.1: Graph showing the number of CST sessions run by participants



Across the STANDOUT and MONOU trials 72 participants were involved in the delivery of the maintenance CST programme. Out of the 72 participants 46% delivered between 1-8 sessions, 25% of participants ran between 9-16 sessions and 29% of participants delivered 17-24 sessions.

Figure 10.2: Graph showing number of maintenance CST sessions run by participants



These figures do not reflect the successfulness of delivering the full programme as not all centres ran the full 24 week programme. Three centres ran a 16 week maintenance CST programme, two centres ran a 23 week programme, one centre delivered a 22 week programme, one centre ran a 17 week programme, one centre delivered a 12 week programme and one centre offered a six week maintenance CST programme. So, within the trial there was variation in the length of delivery of the programme. This occurred due to pragmatic reasons such as; lack of staff or group members, annual leave, public holidays, and lack of resources. Also, for many services the maintenance CST programme was a 'new' element in their delivery of the programme and so staff were not used to delivering an intervention for a substantially longer period of time, and did not feel they had the capacity to continue with the programme for a sustained amount of time. In contrast to the delivery of the CST programme there was less involvement by participants in the delivery of the maintenance CST programme.

The numbers reported in this study in the delivery of the programme see that staff numbers for each group range from one to six, that created in some instances a one to one programme that has not been considered before. The increased staff numbers demonstrated in this study would have implications for the resourcing and costing of the delivery of the CST and maintenance programme. However, the variation in staff delivering the CST and maintenance CST programme may be due to the high rates of staff turnover that is documented as a persistent problem (Castle, Engberg, & Men., 2007), with previous national estimates of retention and turnover of staff indicating an annual turnover rate in nursing homes to be at its highest (Donoghue, 2010). The high level of turnover, and amalgamation of services is a reality in healthcare, and was evident in this study. This is demonstrated as 33 (32.7%) out of 101 participants left their job and dropped out of the trial. It also became apparent that entire centres withdrew from the research as opposed to

individuals. This tended to occur when the centre was unable to run the programme, as they did not see the purpose to them remaining in the trial. In total 10 out of 63 centres withdrew due to this reason.

The length of the STANDOUT and MONOU trials was decided by considering how long one might be expected to set up and plan the running of the programme. It was felt that three months was a sufficient amount of time for the set up of the programme to occur. The CST programme was originally designed to run for seven weeks and the maintenance CST programme for 24 weeks. So 31 weeks in total, or just under eight months to run the entire programme. When it became clear that in some centres the CST programme would run once a week for 14 weeks, the timeframe of a year also accounted for this variation.

For the observational study the people with dementia were recruited for 31 or 38 weeks depending on the delivery of the CST programme. However, this did not take into account any variation in the delivery of the programme such as breaks between the delivery of the CST and maintenance CST programme. Due to unscheduled breaks in the delivery of the programme, participants remained in the study for longer than anticipated, or received a shortened version of the programme.

10.5.7 Researcher bias

It is worthwhile to consider the position of ASt as the lead researcher in this study. The role of ASt included completion of the ethics application, recruitment, reminders for follow ups assessments, undertaking assessments with people with dementia, and development and delivery of CST training and outreach support. In addition, both academic supervisors are experts in the field of CST and have been involved in the development, piloting, and evaluation of the intervention. Although the research study was regularly reviewed at Programme Steering Committee meetings, further evaluation of the outreach support options may have

been advantageous for the evaluation of the intervention used in the main trials.

10.6 Effects of the intervention

The MRC framework (2000, 2008) provided a useful framework in the development of CST and maintenance CST to the point where it could be considered that the intervention would have a worthwhile effect. In the STANDOUT and MONOU trial the ITT analysis demonstrated that staff members were more likely to implement the maintenance CST programme leading on from the CST programme, if they were in receipt of the outreach support. However, if the percentage of groups run following on from CST is calculated, the percentage worked out at the same for the outreach support and no outreach support group (67%). As the analysis was based on the combined numbers of those CST groups that were delivered and those that were not delivered, those in receipt of outreach support were higher (12/23), compared to the no outreach support group (8/20). This original analysis should be interpreted with caution as it combined the numbers of those that did and did not run groups. So, the additional outreach support demonstrated no effect during the CST phase of the intervention, but may be useful in the on-going lengthier nature of the maintenance CST programme.

When comparing the implementation of the CST programme with previous CST uptake research, 35.6% people went on to run CST after attending the one day CST training. To compare this to a similar group of those staff in the STANDOUT trial, 17 out of 50 (34%) went on to run CST after the training. This is an interesting finding as irrespective of research involvement the uptake of CST is similar across groups, and this appears unchanged even though staff agreed to have the intention to run the CST programme, so might be expected to be higher. Perhaps indicating that it is the external factors to the running of the group, such as organisational

and staff issues that have a greater influence on the implementation of the programme in practice.

The sample size of the STANDOUT and MONOU trial was powered on the uptake of outreach support as opposed to the difference of, or the offer, of outreach support. These are slightly different questions and in turn the dataset cannot be relied on to answer all questions. In terms of the secondary outcomes anything else would have been exploratory. However, as the outreach support was minimally used, it is perhaps unsurprisingly that there were no differences between those in receipt of outreach support and those that were not in relation to these measures.

The STANDOUT and MONOU trial pragmatically evaluated the effectiveness of staff training and outreach support but did not show a significant effect on the primary or secondary outcomes. The failure of training and outreach support intervention to have a positive impact on outcome measures may reflect the difficulties inherent with changing the culture of care (Fossey et al., 2006). However, it is worth noting with the addition of outreach support there was an overall increase in the delivery of maintenance CST in both new CST practitioners (STANDOUT) and experienced CST practitioners (MONOU). The MONOU trial provided a naturalistic evaluation of benefits of manual only versus manual and training in CST implementation, and both the STANDOUT and MONOU trial identified staff and situational factors that impede or facilitate CST implementation. It also allowed the research to demonstrate, on a large scale nationwide, the knowledge, views and understanding, and approaches of staff members to dementia in a variety of care settings with the use of the secondary outcome measures.

Cognition improved for participants in the observational study that met the inclusion criteria (less than 25 on the MMSE) between BL and FU1 (before and after CST). When comparing to a similar population in a TAU

group (Spector el al., 2003) the participants increased by 1.4 points on the MMSE as there was a 0.4 decrease in the TAU group. This finding was statistically significant (p=0.04) and demonstrated benefit for people with dementia to participate in the CST programme compared to TAU and overall cognition remained unchanged between BL and FU2 (after maintenance CST). Just under a four-point decrease in MMSE score is expected over a year time frame (Clark et al., 1999) and so this finding was also considered a beneficial outcome to participating in the maintenance CST programme.

For QoL there was a 0.9 point decrease between BL and FU1, and this effect was not considered significant. However, between BL and FU2 there was a .01 point increase, but this again was not statistically significant. When participants that met the inclusion criteria of mild to moderate dementia, as rated by the MMSE, were analysed there was a one point increase on the QoL measure. Previous research demonstrated QoL to remain unchanged after a year (Selwood, Thorgrimsen & Orrell., 2005), in contrast the CST programme followed by the maintenance CST programme demonstrated a slight improvement in self rated QOL, so this is a positive finding.

When the ANCOVA analysis was applied to the dataset the frequency of CST demonstrated a benefit for those in receipt of the intervention once weekly. However, the small sample size does not account for the amount of variability, and would require a much larger sample size in order to account for this. Subsequently, these findings need to be interpreted with caution until a larger observational study taking this variation into account can be carried out.

The intervention of outreach support does not demonstrate a statistical significance in the primary outcome between the two groups. As outreach support was rarely accessed this was to be expected. Local supervision

as an outreach support was for the majority of instances initiated by ASt (75%) and had the monthly FU phone calls not occurred, these queries might not have been recorded. This research study showed a similar uptake of CST (1:3) after one day training for the STANDOUT participants, compared to the previously conducted pilot study (Spector et al., 2011). Yet, if the running of CST observed in the trial is based on the intervention group or not, those in receipt of outreach support (across STANDOUT & MONOU) increased in the uptake of CST to 51% and those centres in TAU had a 43% uptake of the CST programme. Although, not statistically significant the outreach support may have increased the uptake of CST, or it may also have been their research involvement that inflated this figure. However, one might expect that this initial effort of running the programme may have dwindled by the time of implementing the maintenance CST programme. This trial demonstrated that with the additional outreach support the centres were more likely to run maintenance CST following on from the original programme. Further research is required to determine the usefulness of outreach support in the delivery of the CST and maintenance CST programme.

10.7 Comparison with past research

The STANDOUT and MONOU studies used a variety of non qualified and qualified dementia care staff. The recruitment of care staff and day centre staff into the trial was consistent with previously conducted CST research (Spector et al., 2003; Orrell, Spector, Thorgrimsen, & Woods, 2005; Aguirre et al., 2010). The other occupational demographics represented in the study sample were also supported in a pilot study that reported the job titles of staff that had attended previous CST training and uptake of CST (Spector, Orrell, & Aguirre, 2011).

Research based specifically on CST as an intervention has used the brief LTSI and ADQ (Spector, Orrell, & Aguirre, 2011). As this was a small scale pilot study it was necessary to apply these measures to a larger sample

size. The pilot study also recommended the use of a competence measure to determine if this influenced the delivery of the programme, so the SCIDS was considered a useful tool to determine this (Schepers, Orrell, Shanahan, & Spector, 2012).

The observational study results can be well compared with previously conducted CST research, as the same inclusion criteria was used across all of the research studies. In the original CST trial there was a 0.9 point increase on the MMSE for those participants that received the CST programme and in a more recent study there was a 1.1 point increase for those participants that received CST as TAU (Orrell et al., 2014). When the inclusion criteria checklist was adhered to, for the observational study, there was a mean increase of one point on the MMSE. This demonstrated that in practice CST delivered by staff can be as effective as when delivered in a research capacity (researcher delivered), and this falls in line with previously conducted CST research.

10.8 Limitations of the study

The trial followed the framework for the development and evaluation of complex interventions and aimed to meet the 'gold standards' of clinical trials. However, similarly to other trials there were a variety of biases (section 10.2.6) and this needs to be taken into consideration when discussing the results.

The centres that participated in the observational study were required to run the CST and maintenance CST programme as defined in the published 'Making a difference' and 'Making a difference 2' manuals. The programme is clearly defined and structured in both manuals. However, due to the nature of the programme being person centred and catering to the individual needs of the group, this created variability in the delivery of the programme that is hard to control for.

Arguably, in the observational study it would have been useful to have a control group to make a direct comparison with the participants attending the CST programme. However, as CST is a NICE recommended therapy (2006) and the programme was run as part of usual practice it would have deprived participants from receiving CST, as opposed to previous research where the therapy has been in addition to TAU.

10.9 Future research

The focus of the STANDOUT and MONOU trials has been to measure the effect of outreach support on the delivery of the CST and maintenance CST programme. An element of outreach support that was not utilised for this trial was having direct supervision in the delivery of the programme with a person familiar with CST supporting the delivery of the intervention. This was researched further through a service evaluation carried out in the London Borough of Redbridge (Chapter 8) with staff in 14 care homes. The care homes had regular contact with ASt and EA and received three to four home visits to observe the CST groups in action and provide constructive feedback if and when required. This service evaluation demonstrated improvements in the amount of CST programmes run (50%) improvements in dementia care practice, as well as improved sense of competence. Due to these perceived benefits it would be useful to run an RCT with direct supervision in a variety of dementia care settings to determine if this effect can be replicated on a larger scale and this is supported by a focus group member feeding back that ‘it would have been lovely if you had came out and seen us’ (FG4).

The primary outcome measure for the STANDOUT and MONOU trial was the number of attendees to the programme, and the running of the sessions was monitored through the attendance and adherence booklets. For the purposes of this study a third of booklets were analysed to determine the common key principles that were not adhered to, as detailed in the adherence checklist. This way of record keeping is a

subjective measure of adherence as recorded by the staff members. To better understand the level of adherence to the CST and maintenance CST programme video recording sessions run by staff may be more useful to get a 'truer' picture of how groups are being run in practice. This might also go some way in explaining the level of variation in the delivery of the programme. Anecdotally, staff fed back to ASt that certain elements of the programme were being missed, such as the warm up activity and that sessions were being moved around depending on the interests of the group members. The question needs to be asked, when is CST and maintenance CST as described in the published manuals, no longer CST.

In terms of building on the findings of the observational study it became apparent early on that the programme was being delivered once weekly, as well as twice weekly, and the study was not powered to take this variation into account. More recently, an evaluation was carried out looking at the effectiveness of a once weekly CST programme (Cove et al., 2013). Cove and colleagues (2013) found that there were no positive changes in cognition or QOL for those participants receiving the programme once weekly. However, in this study those participants that received the same frequency in the delivery of the programme improved in cognition between BL and FU1. This discrepancy between the two studies should be researched further to determine what additional factors might impact on the outcomes measured with the person with dementia. It is important to identify these factors as in many services CST is being 'prescribed' but on a weekly basis. The impact in the change of delivery of the CST programme remains unclear as to whether there is benefit to the person, and this has implications not only for them, but also in terms of cost effectiveness and the demand put on services.

The delivery of the programme in the observational study was very much dependent on the availability of staff, and the demands on the services as

a whole. This flexibility in the delivery of the programme was reflected in the time between FU. Although the study was still able to demonstrate a positive benefit in cognition for the person with dementia, when compared to a TAU group it may be useful to carry out a similar study but with more rigidity in the delivery of the programme, with a record of attendance and adherence, to give a direct comparison between previous research that has been researcher led and the effect of staff led groups.

Another development of CST is for those unable to attend a group programme by having an individualised version of CST. The development of individual CST (iCST) programme (Orrell et al., 2012) for people with dementia and their carer is on a one to one basis for those living in the community. This was developed and adapted from the group programme through the use of focus groups and consensus conferences to create a manual, workbook and toolkit. The research team also created training for the family member and offered on-going support. The programme has also been developed to include a training DVD to help demonstrate the therapy to people in their homes. The trial was designed as a multi-centre, pragmatic RCT comparing the effectiveness and cost-effectiveness of iCST for people with dementia compared to treatment as usual. The design of the intervention was to be delivered three times a week for 30 minutes over a 25-week period. Similarly to previous CST research the key outcomes were cognition and QoL for the person with dementia, and QoL for the carer delivering the programme. The trial has now finished and is currently being analysed. This development will go some way in determining how successful the CST programme is on a one to one basis and the effect this has on the person with dementia and their family caregiver.

10.10 Implications for practice

This trial has followed the MRC framework for complex interventions by focussing on the implementation and dissemination stage of the

framework. Arguably, the trial has been marginally optimistic in trying to account for covariates that might impact on the outcome of the study. Even though ASt was aware of the contextual variables in a healthcare setting with issues such as reorganization and policy change, it was not possible to control for this. The secondary outcome measures provided a useful overview of staff perceptions and knowledge before, during and after the research study and there was an indication that the external situational factors impeded on the running of the CST and maintenance CST programme.

This research project has demonstrated the level of variability of getting CST from a research setting into practice. As identified in previous research (Grimshaw & Eccles, 2004; Grol et al., 2007) external factors have limited the successfulness of implementation in dementia care settings. In the development of the trial, and throughout the research process, the delivery and implementation of CST has been key. Monthly FU reminders, and the availability of training resources supported this, as well as multi-faceted outreach support options to increase the uptake and successful implementation of the programme.

The observational study provided an evaluation of long term cognitive and QoL benefits of CST and maintenance CST in practice. It is the first study to measure outcome measures with people with dementia when it is staff members only that are delivering CST and maintenance CST as part TAU. Benefits in cognition were demonstrated between BL and FU1 (after CST) and this is similar to previous CST research. This is useful to strengthen the message of the NICE guidelines for people to participate in a group structured cognitively stimulating programme.

10.12 Conclusion

The primary aim of the STANDOUT and MONOU trials was to identify if the option of outreach support would increase the level of attendance to the CST and maintenance CST programme. This research appears unique, in that it is the first large piece of research to investigate the implementation and long-term dissemination of CST, in line with phase IV of the MRC framework for complex interventions. It is one of few studies to systematically review the reporting of cognitive stimulation, and is unique as the review goes one step further by applying the newly devised 'ImpRess' scale to evaluate the interventions implementation readiness, and applicability outside the research sphere of academia.

Notably, this trial has demonstrated on a large scale that minimal support of staff members in a variety of care settings can maintain the delivery of the maintenance CST. Although training was highlighted as a preferred option to run the programme this did not seem to impact on the quality of programme delivered to group members.

In the observational study the main aim was to determine whether the benefits to cognition and QoL could be replicated in practice. Importantly, staff led programmes indicated that cognition and QoL for the person with dementia in receipt of CST and maintenance CST can be maintained throughout the delivery of the programme. In line with previous comparisons of CST to TAU the delivery of CST provides significant benefits in cognition for the person with dementia.

Importantly, it is one of the first studies to examine the level of variability and flexibility in the delivery of the CST programme. Although not all these variations could be monitored for and included in the analysis, benefits for the person with dementia were still demonstrated when the programme was run once weekly. Although, this was seen with a small sample size, the potential flexibility of the programme with the same

positive outcomes for the person with dementia is a positive finding. This flexibility in the delivery of the programme also extends to, the set up of the programme, inclusion criteria for group members, omission or amendments of particular sections of the session, and these elements are required to be researched further. Clear guidance could then be provided in relation to the level of malleability of the programme, for it to still demonstrate benefits for the person with dementia.

However, there are limitations. Notably, the small sample size for the observational study makes it difficult to determine with certainty that the once weekly delivery of the CST programme is as beneficial as the original format of the twice weekly programme. In addition, the comparison between participants in receipt of CST in this research study and the TAU group in past research has its drawbacks. The original study was published in 2003, and over a decade later what was considered TAU then, may differ today.

The MONOU trial had a small sample size and so any direct comparisons with the STANDOUT trial has to be treated with caution. In addition, the generalisability of findings for this trial, as well as the observational study, might be constrained due to the homogeneity of the sample, being predominantly white and female. Despite these limitations, the trial has important practical and clinical implications. Practically, getting CST into practice can be impacted by external factors, but can be supported in the long term by the addition of outreach support. Clinically, results demonstrate the improvements to cognition in the short term, and maintenance of cognition and QoL in the long term for the person with dementia. These results support the continuing use, and widespread dissemination of CST.

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Appendices

Appendix 1: Ethics letters

Appendix 1.1: REC Approval

NHS
National Research Ethics Service
NRES Committee London - East
REC Offices
Room 10
4th Floor West
Charing Cross Hospital
Fulham Palace Road
London
W6 8RF

Telephone: 020 7794 0500 x34836

14 June 2011

Professor Martin Orrell
Professor of Ageing and Mental Health
University College London
Dept. of Mental Health Sciences
Charles Bell House
67-73 Riding House Street, London
W1W 7EJ

Dear Professor Orrell

Study title:	**An Evaluation and Comparison of the Effectiveness of Two Different CST Training Approaches and Their Implementation in Practice.**
REC reference:	**11/LO/0059**
Protocol number:	**RP-PG-0606-1083**

Thank you for your letter of 18 May 2011, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon

as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Advertisement	3	20 January 2011
Evidence of insurance or indemnity		08 July 2009
GP/Consultant Information Sheets	1	26 January 2011
Investigator CV		04 May 2009
Letter from Sponsor		20 January 2011
Other: summary for CV- student		20 October 2010
Other: letter from funder		08 March 2007
Other: Referee's or other scientific critique report-peer review form 1		11 December 2006
Other: Referee's or other scientific critique report- peer review form 2		11 December 2006
Other: Referee's or other scientific critique report- peer review form 3		11 December 2006
Other: Referee's or other scientific critique report- peer review form 4		11 December 2006
Other: summary of protocol in non-technical language- Study one (RCT) plan and assessment schedule	1	
Other: summary of protocol in non-technical language- Study two plan and assessment schedule	1	
Other: summary of protocol in non-technical language- Study three plan and assessment schedule	1	

Participant Consent Form: management consent form	1.3	26 January 2011
Participant Consent Form: consent form filming DVD	1	24 February 2011
Participant Consent Form: Staff	1.4	03 May 2011
Participant Consent Form: Participant	1.4	03 May 2011
Participant Information Sheet: Mangagement	1.5	26 January 2011
Participant Information Sheet: Participant	1.5	03 May 2011
Participant Information Sheet: Staff	1.5	26 January 2011
Participant Information Sheet: Management	1.5	03 May 2011
Participant Information Sheet: Staff	1.5	03 May 2011
Protocol	3.3	25 January 2011
Questionnaire: AChEI Questions		
Questionnaire: Inclusion criteria maintennance staff training	v1	
Questionnaire: Mini Mental State Examination		
Questionnaire: Quality of life in Alzheimer's disease		
Questionnaire: thoughts about challenging behaviour		
Questionnaire: Dementia knowledge 20 (DK20)		
Questionnaire: Sense of Competance Dementia- Staff (SOCID-S)		
Questionnaire: Approaches to dementia questionnaire		
Questionnaire: Minnesota satisfaction questionnaire		
Questionnaire: Brief Learning Transger System Inventory (BLTSI)		
Questionnaire: Monitoring progress		
Questionnaire: Adherence to maintenance CST staff training	1	
REC application	11/lo/0059	10 March 2011
Response to Request for Further Information		18 May 2011

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

Notifying substantial amendments
Adding new sites and investigators
Progress and safety reports
Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

11/LO/0059	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

P V Keegan

Revd Dr Joyce Smith
Chair

Email: laura.keegan@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: Miss Fiona Horton
Ms Sandeep Toot, North East London Foundation Trust

Appendix 1.2: REC Amended Approval

NRES Committee London - East
REC Offices
Room 10
4th Floor West
Charing Cross Hospital
Fulham Palace Road
London
W6 8RF

12 July 2011 *(Revised- amended document dates)*

Professor Martin Orrell
Professor of Ageing and Mental Health
University College London
Dept. of Mental Health Sciences
Charles Bell House
67-73 Riding House Street, London
W1W 7EJ

Dear Professor Orrell

Study title:	**An Evaluation and Comparison of the Effectiveness of Two Different CST Training Approaches and Their Implementation in Practice.**
REC reference:	**11/LO/0059**
Protocol number:	**RP-PG-0606-1083**

Thank you for your letter of 18 June 2011, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Advertisement	3	20 January 2011
Evidence of insurance or indemnity		08 June 2009
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Other: summary for CV- student		20 October 2010
Other: letter from funder		08 March 2007
Other: Referee's or other scientific critique report-peer review form 1		11 December 2006
Other: Referee's or other scientific critique report- peer review form 2		11 December 2006
Other: Referee's or other scientific critique report- peer review form 3		11 December 2006
Other: Referee's or other scientific critique report- peer review form 4		11 December 2006
Other: summary of protocol in non-technical language- Study one (RCT) plan and assessment schedule	1	
Other: summary of protocol in non-technical language- Study two plan and assessment schedule	1	
Other: summary of protocol in non-technical language- Study three plan and assessment schedule	1	
Participant Consent Form: management consent form	1.3	26 January 2011
Participant Consent Form: consent form filming DVD	1	24 February 2011
Participant Consent Form: Staff	1.4	03 May 2011

Participant Consent Form: Participant	1.4	03 May 2011
Participant Information Sheet: Mangagement	1.5	26 January 2011
Participant Information Sheet: Participant	1.5	03 May 2011
Participant Information Sheet: Staff	1.5	26 January 2011
Participant Information Sheet: Management	1.5	03 May 2011
Participant Information Sheet: Staff	1.5	03 May 2011
Protocol	3.3	25 January 2011
Questionnaire: AChEI Questions		
Questionnaire: Inclusion criteria maintennance staff training	v1	
Questionnaire: Mini Mental State Examination		
Questionnaire: Quality of life in Alzheimer's disease		
Questionnaire: thoughts about challenging behaviour		
Questionnaire: Dementia knowledge 20 (DK20)		
Questionnaire: Sense of Competance Dementia- Staff (SOCID-S)		
Questionnaire: Approaches to dementia questionnaire		
Questionnaire: Minnesota satisfaction questionnaire		
Questionnaire: Brief Learning Transger System Inventory (BLTSI)		
Questionnaire: Monitoring progress		
Questionnaire: Adherence to maintenance CST staff training	1	
REC application	11/lo/0059	10 March 2011
Response to Request for Further Information		18 June 2011

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

11/LO/0059	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

Revd Dr Joyce Smith
Chair

Email: laura.keegan@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Miss Fiona Horton*
Ms Sandeep Toot, North East London Foundation Trust

Appendix 1.3: North East London Foundation Trust R&D Approval

NHS

North Central London Research Consortium

North Central London Research Consortium
3rd Floor, West Wing
Camden PCT, St Pancras Hospital
4 St Pancras Way, London, NW1 0PE

Telephone: 020 3317 3757

Facsimile: 020 3317 3760
www.camdenproviderservices.nhs.uk

Professor Martin Orrell
North East London Foundation Trust
Department of Mental Health
1st Floor 67-73 Riding House Street
Charles Bell House,
London W1W 7EJ

12th July 2011

Dear Professor Orrell,

Title: An Evaluation and Comparison of the Effectiveness of Two Different CST Training Approaches and Their Implementation in Practice.

REC Ref: 11/LO/0059

I am pleased to confirm that the above study has now received R&D approval, and you may now start your research in **NHS NELFT** May I take this opportunity to remind you that during the course of your research you will be expected to ensure the following:

- **Patient contact:** only trained or supervised researchers who hold the appropriate Trust/NHS contract (honorary or full) with each Trust are allowed contact with that Trust's patients. If any researcher on the study does not hold a contract please contact the R&D office as soon as possible.
- **Informed consent:** original signed consent forms must be kept on file. A copy of the consent form must also be placed in the patient's notes. Research projects are subject to random audit by a member of the R&D office who will ask to see all original signed consent forms.
- **Data protection:** measures must be taken to ensure that patient data is kept confidential in accordance with the Data Protection Act 1998.
- **Health & safety:** all local health & safety regulations where the research is being conducted must be adhered to.
- **Adverse events:** adverse events or suspected misconduct should be reported to the R&D office and the Ethics Committee.
- **Project update:** you will be sent a project update form at regular intervals. Please complete the form and return it to the R&D office.
- **Publications:** it is essential that you inform the R&D office about any publications which result from your research.
- **Ethics:** R&D approval is based on the conditions set out in the favourable opinion letter from the Ethics Committee. If during the lifetime of your research project, you wish to make a revision or amendment to your original submission, please contact both the Ethics Committee and R&D Office as soon as possible.

Please ensure that all members of the research team are aware of their responsibilities as researchers. For more details on these responsibilities, please check the R&D handbook or NoCLoR website:
http://www.noclor.nhs.uk

We would like to wish you every success with your project

Yours sincerely,

Angela Williams
R&D Manager

Appendix 1.4: Northampton Healthcare NHS Trust R&D Approval

Northamptonshire Healthcare NHS
NHS Foundation Trust

Research and Development
Bevan House
Kettering Parkway south,
Venture Park
Northamptonshire,
NN15 6XR

Direct Dial: (01536) 480 314
Fax No: (01536) 480 33

Associate Medical Director: Dr Sean Scanlon

Head of Quality Support: Rose Patrick

R&D Manager: Stephen Zingwe

24/07/12

Professor Martin Orrell
Mental Health Sciences,
1st Floor Charles Bell House,
67-73 Riding House Street,
London
W1W 7EJ

Ref: CSP: 61425
Title: An evaluation and Comparison of the Effectiveness of Two Different CST Training Approaches and their Implementation in practice.
Project Status: Approved
End Date: 28/12/2012

Dear Martin Orrell

Northamptonshire Healthcare Foundation Trust have reviewed the documents submitted which include the SHIELD (**CSP 16378**) study application, REC approval letter for SHIELD **(REC REF: 09/H0701/54 DATE: 15/07/09**), NHFT Trust Approval letter for SHIELD (**NFT REF: R.111.10 DATE: 04/04/11**) and REC Approval for **CSP: 61245** (**REC REF: 11/LO/0059 DATE: 14/06/11).** We are happy to given Trust Permission for this study based on its inclusion in the SHIELD study application and approval.

I am pleased to confirm that with effect from the date of this letter, the above study now has Trust Research & Development permission to commence at Northamptonshire Healthcare NHS Foundation Trust.

All documents approved by The Research Ethics Committee have been reviewed and form part of the approval. The documents received and approved are as follows:

Documents	***Version***	***Date***	***REC Approval***
REC Favourable Opinion Letter	N/A	14/06/11	N/A
Advertisement	3	20/01/11	YES

GP/Consultant Information Sheets	1	26/01/11	YES
Other: Summary of protocol in non-technical language- Study one (RCT) plan and assessment schedule	1	N/A	YES
Other: Summary of protocol in non-technical language- Study two plan and assessment schedule	1	N/A	YES
Other: Summary of protocol in non-technical language- Study three plan and assessment schedule	1	N/A	YES
Participant Consent Form: management consent form	1.3	26/01/11	YES
Participant Consent Form: consent form filming DVD	1	24/02/11	YES
Participant Consent Form: Staff	1.4	03/05/11	YES
Participant Consent Form: Participant	1.4	03/05/11	YES
Participant Information Sheet: Management	1.5	26/01/11	YES
Participant information sheet: Participant	1.5	03/05/11	YES
Participant information sheet: Staff	1.5	26/01/11	YES
Participant information management	1.5	03/05/11	YES
Participant information sheet: Staff	1.5	03/05/11	YES
Protocol	3.3	25/01/11	YES
Questionnaire: AChEI Questions	N/A	N/A	YES
Questionnaire: Inclusion criteria maintenance staff training	1	N/A	YES
Questionnaire: Mini Mental State Examination	N/A	N/A	YES
Questionnaire: Quality of life in Alzheimer's disease	N/A	N/A	YES
Questionnaire: thoughts about challenging behaviour	N/A	N/A	YES
Questionnaire: Dementia knowledge 20 (DK20)	N/A	N/A	YES
Questionnaire: Sense of competence dementia-staff (SOCID-S)	N/A	N/A	YES
Questionnaire: Approaches to Dementia Questionnaire	N/A	N/A	YES
Questionnaire: Minnesota Satisfaction Questionnaire	N/A	N/A	YES
Questionnaire: Brief Learning Transfer System Inventory (BLTSI)	N/A	N/A	YES
Questionnaire: Monitoring progress	N/A	N/A	YES
Questionnaire: Adherence to maintenance CST staff training.	1	N/A	YES

Please be aware that any changes to these documents after approval may constitute an amendment. The process of approval for amendments should be followed. Failure to do so may invalidate the approval of the study at this trust.

We are aware that undertaking research in the NHS comes with a range of regulatory responsibilities. Attached to this letter is a reminder of your responsibilities during the course of the research. Please ensure that you and the research team are familiar with and understand the roles and responsibilities both collectively and individually.

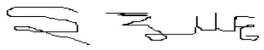
You are required to submit an annual progress report to the R&D Office and to the Research Ethics Committee. We will remind you when this is due.

The R&D Office is keen to support research, researchers and to facilitate approval. If you have any questions regarding this, or other research you wish to undertake in the Trust, please contact this office.

Please note that some of the documents may not apply to your study.

We wish you every success with your research.

Yours sincerely



Stephen Zingwe
Research and Development Manager

Encs: Researcher Information Sheet

Please note that some of the documents may not apply to your study.

Appendix 1.5: Tees, Esk & Wear Valleys NHS Foundation Trust R&D Approval

- Early termination of the study, or continuation beyond the stated end date
- Significant adverse events
- Significant amendments to the study protocol

The Trust R&D Office conducts a yearly audit of research governance compliance, and you will be informed in advance if this study is due to be audited.

I would like to take this opportunity to wish you every success with your research. If there is any way that we can assist you in the future please contact us.

Yours sincerely

Hilary Allan
R&D Manager

Cc Alison Bullock
Amy Streater

Appendix 1.6: Nottinghamshire Healthcare NHS Trust R&D Approval

Nottinghamshire Healthcare NHS
NHS Trust

Positive about mental health and learning disability

Research Management and Governance
Institute of Mental Health
2nd Floor, Duncan MacMillan House
Porchester Road
Nottingham

25th May 2012

Professor Martin Orrell
University College London
Department of Mental Health
1st Floor 67-73 Riding House Street
Charles Bell House
London
W1W 7EJ

Dear Prof. Orrell

Summary of the Study

Title: An Evaluation and Comparison of the Effectiveness of Two Different CST Training Approaches and Its Implementation in Practice
REF: 11/LO/0059

Objectives
This application is part of the SHIELD programme; a 5 year grant funded NIHR programme on psychosocial interventions in dementia. The objective of the study is to examine the effectiveness of Maintenance Cognitive Stimulation Therapy (CST).

Recruitment/Methodology
CST will be offered for a total of 31 weeks to dementia patients; 7 weeks @ 2 sessions per week followed by a maintenance phase of 24 weeks @ 1 session per week. Sessions will last approx. 1 hour involving 5-8 patients and facilitated by 2 dementia staff.

The study is comprised of 3 different studies, however only studies 2 and 3 will be conducted at this site.
Study 2: Staff delivering CST will be randomised (50:50) to receive web-based outreach support: no outreach support. Staff will be asked to complete a questionnaire at baseline and at a six and twelve month follow up.
Study 3: Staff delivering CST will be approached to complete a cognition and quality of life measure with dementia patients when they start the CST sessions, after week 7 and after the maintenance CST sessions have been carried out.

Outcomes
This research programme aims to reduce disability, improve health outcomes and enhance quality of life of people with dementia and their caregivers. This study will compare the benefits of CST with maintenance against CST only without ongoing maintenance.

Thank you for submitting the above project to the Nottinghamshire Healthcare NHS Trust's R&D Department. The project has now been given Organisational Approval by:

Dr Peter Miller, R&D Lead, on behalf of Nottinghamshire Healthcare NHS Trust

Conditions of approval
Please note that approval for this study is dependent on full compliance with the following.

- All members of the research team should familiarise themselves with all relevant policies and procedures, including the Trust policy GG/CG/04 – staff conducting, hosting or collaborating in research (note, currently being revised).

- The Chief Investigator, and all other members of the research team, should comply with any regulations applicable to the study, including, but not limited to: The NHS Research Governance Framework for

Health and Social Care (2005), The Declaration of Helsinki (2000), The UK Medicines for Human Use (Clinical Trials) Regulations (2004), ICH Good Clinical Practice guidelines (1997), The Human Tissue Act (2004), The Data Protection Act (1998), The Mental Capacity Act (2005).

- The Chief Investigator should ensure that all members of the research team are suitably qualified and experienced, and adequately supervised. This should include training in informed consent procedures and GCP, where necessary.
- Research governance should be notified within the same timeframe of notifying REC of any major changes to the study, which may include changes to the team, requiring honorary contracts or letters of access to be issued, changes to timescales or changes in procedures.
- Any changes in the protocol or documentation should be approved by the ethics committee and research governance.
- Care professionals should be informed of their patients' participation in the research.
- The protocol should be adhered to; any deviations should be notified to research governance.
- Suitable arrangements for archiving should be made in accordance with the guidelines of the sponsor, and research governance should be kept informed of any changes or failures in archiving arrangements, including failures in safe preservation of electronic data. Failure to report such losses will result in disciplinary investigation of Trust staff, and a disciplinary enquiry of external researchers, which could result in the rescinding of rights to carry research in the Trust.

The *Research Governance Framework for Health & Social Care* sets out the responsibilities of all those involved in research in order to enhance the ethical and scientific quality of health research and to safeguard patients and the public. The lead investigator and all involved in the research have a responsibility to comply with Research Governance.

Full details can be found in the RGF document available at www.dh.gov.uk or via the Research and Evaluation Department.

Yours sincerely,

Shirley Mitchell
Head of Research Management and Governance

Copy to
Ms Amy Streater
Ms Fiona Horton – Sponsor
Ms Clare Litherland – Local Collaborator

Appendix 1.7: North Staffordshire NHS Trust R&D Approval

Approval by the R&D Department therefore assumes that you have read, understand and agree to comply with the following:-

- Research Governance Framework (www.doh.gov.uk/research)
- ICH Guidelines on Good Clinical Practice
- Data Protection Act 1998
- Mental Capacity Act 2007
- Medicines for Human Use (Clinical Trials) Regulations 2004
- Human Tissue Act 2004
- All applicable Trust policies & procedures

In line with these requirements, may I draw your attention to the need for you to provide the following documentation/notifications to the R&D Office throughout the course of the study, and that all amendments (including changes to the local research team) need to be submitted to, and approved by R&D, in accordance with IRAS guidance:-

- Annual Progress Report Form (sent to you by the R&D Office)
- End of Study Declaration Form (available via IRAS)
- End of Study Report (produced by the Chief Investigator)
- Changes to study start and end dates
- Changes in study personnel

Please note that this NHS organisation is required to monitor research to ensure compliance with the Research Governance Framework, and other legal and regulatory requirements. This will be achieved by random audit conducted by this department.

I would like to take this opportunity to wish you well with your research. If you need any further advice or guidance please do not hesitate to contact us.

Yours sincerely

Professor Peter Crome
R&D Director – North Staffordshire Combined Healthcare NHS Trust

Copies to:

Appendix 1.8: Kent & Medway NHS Trust R&D Approval

NHS
National Institute for Health Research
RM&G Consortium for Kent & Medway
CLRN
No 6, The Courtyard
Campus Way
Gillingham Business Park
Kent ME8 0NZ
Phone: 01622 227361
Email: pdodds2@nhs.net
http://kent-medway.crncc.nihr.ac.uk

Ms Alison Culverwell
Consultant Clinical Psychologist & Head of Psychological Services
Psychological Services
Gregory House,
St Martins Hospital,
Littlebourne Road
Canterbury, CT1 1TD

2nd July 2012

Dear Ms Culverwell,

Permission for research

I am writing to inform you that the NHS organisation listed below has granted permission for the following research project on the basis described in the application form, protocol and supporting documentation.

Please note that the local study team should inform patient participants, as part of the valid informed consent process, of the discrepancy between the CST schedule described in the Participant Information Sheet and the standard local treatment schedule. A file note detailing this should be place on the investigator site file and the study Sponsor informed.

Study details:

Study Title	An Evaluation and Comparison of the Effectiveness of Two Different CST Training Approaches and Its Implementation in Practice
Chief Investigator	Professor Martin Orrell
Sponsor name	North East London Foundation Trust
K&M CLRN study number	12-038
Sponsor's reference number	NA
IRAS or UKCRN ID number	61425
REC number (REC name)	11/LO/0059; London East REC
EudraCT number	NA

The RM&G Consortium for Kent & Medway provides services to NHS Kent and Medway, Kent Community Health NHS Trust, Medway Community Healthcare CIC, Kent & Medway NHS & Social Care Partnership Trust and South East Coast Ambulance NHS Trust

NHS organisation and location:

Organisation giving permission	Date of Permission	Sites to which permission applies
Kent and Medway NHS and Social Care Partnership Trust	02/07/2012	-Thanet Community Health Team for Older People, The Lydden Unit -Swale Community Mental Health Team and day Services for Older People -St Martin's Hospital, Canterbury -Highlands House, Tunbridge Wells -Elizabeth House, Rainham -Priority House, Maidstone -Other sites yet to be identified.

The documents reviewed were:

Document	Version	Date
IRAS R&D form	61425/310600/14/31	
SSI form	61425/314953/6/408/127910/241415	
Current version of protocol	3.5	
REC letter of favourable opinion	11/LO/0059	14/06/2012
Supporting documents as listed in the REC letter	Various	Various
Amendments to date	**Amendment number**	**Date**
Non-substantial amendment 01	01	16/03/2012
Non-substantial amendment 02	02	18/04/2012

Permission is granted on the understanding that the study is conducted in accordance with the Research Governance Framework, ICH GCP, The Data Protection Act and NHS Trust policies and procedures. Permission is only granted for the activities for which a favourable opinion has been given by the REC.

The following local conditions will apply

1. **Sponsorship of study** The research sponsor will be the organisation named above; the trust giving permission is not responsible for the management and design of the study.

2. **Confidentiality** You are required to ensure that all information regarding participants remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the Data Protection Act (1998) and the NHS Confidentiality Code of Practice (www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf). Furthermore, you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

3.	**Researcher authorisation**	**Important.** Only those researchers holding a Letter of Access or Honorary Research Contract, as appropriate, from the NHS Organisation may have direct contact with the participants of the study, unless they already hold a substantive or honorary clinical contract with the organisation.
4.	**Amendments**	All amendments (including changes to the local research team) need to be submitted in accordance with guidance in IRAS. This office should be informed at the same time as REC is notified in order to avoid unnecessary delays.
5.	**Indemnity**	You must check with the Sponsor that the indemnity arrangements, as confirmed in the Sponsor's Declaration and described in the application forms, are in place before any participants are recruited.
6.	**Study progression**	You will inform us of any significant developments that occur as the study progresses. You will complete and return any report forms that we send you and provide up-to-date information on the number of participants recruited when asked.
7.	**Audit of Study**	You may also be subject to a random audit of research which will involve a site visit, a requirement to view study documents and a request to interview researchers.
8.	**Study completion**	You will notify the Chief Investigator and this office when the study has completed recruiting participants and when the study is finally finished at your site. You will complete and return the final report that we send you and inform us of any publications relating to the study.
9.	**Presentation of findings.**	Kent and Medway NHS and Social Care Partnership Trust (KMPT) expects that the findings of this study will be presented to members of the appropriate Service Line. You should contact the service line research lead upon completion of the study to arrange a suitable venue and time.

Finally, I wish you every success with the study.

Yours sincerely,

Hazel Crawford

RM&G Manager, RM&G Consortium for Kent and Medway

copies to Professor Martin Orrell
John Brouder (Sponsor's representative)
Sandeep Toot (Study coordinator)

Appendix 1.9: South Staffordshire & Shropshire Healthcare NHSFT R&D Approval

South Staffordshire and Shropshire Healthcare NHS
NHS Foundation Trust

Our Ref: AB/R197

Research and Development
Block 7
St George's Hospital
Corporation Street
STAFFORD
ST16 3AG
Tel: (01785) 221168
Email: Audrey,bright@sssft.nhs.uk

5 March 2012

Professor Martin Orrell
Department of Mental Health Sciences
UCL, Charles Bell House
67-73 Riding House Street
London W1W 7EJ

Dear Professor Orrell

Study title: `Implementation and Evaluation of Two Different CST Training Approach

We have considered your application for access to patients and staff from within this Trust in connection with the above study.

On behalf of the Trust the Lead Officer for Research Governance (Eleanor Bradley), and the Responsible Care Professionals within the Mental Health Directorate have now satisfied themselves that the requirements for Research Governance, both Nationally and Locally, have been met and are happy to give approval for this study to take place in the Trust, with the following provisos:

- That all researchers coming into the Trust have been issued with either a letter of access or honorary contract by ourselves
- That you conform to the requirements laid out in the letters from the REC dated 14 June 2011, which prohibits any changes to the agreed protocol
- That you keep the Trust informed about the progress of the project at 6 monthly intervals
- If at any time details relating to the research project or researcher change, the R&D department must be informed.

Your research has been entered into the Trust database and will appear on the Trust website.

As part of the Research Governance framework it is important that the Trust are notified as to the outcome of your research and as such we will request feedback once the research has finished along with details of dissemination of your findings. You will be asked to provide a copy of the final report and receive an invitation to present final feedback via our research seminar series. To aid dissemination of findings, copies of final reports are placed on our Trust Website. To this end, please contact me towards the completion of the project to discuss the dissemination of findings across the Trust and a possible implementation plan.

If I can help in any other way please do not hesitate to contact me.

Yours sincerely

Professor Eleanor Bradley
Head of Research and Development
Cc Professor Tony Elliott, Shelton Hospital, Bicton Lane, Shewsbury, SY3 8DN

Appendix 2: CST resources

Appendix 2.1: CST training day slides

Removed due to copyright issues

Appendix 2.2: CST training day evaluation form

PLEASE COMPLETE BOTH SIDES

CST TRAINING DAY: EVALUATION FORM

Where appropriate, please tick the box that best suits your opinion 1= very poor, 2 = poor, 3 = average, 4= good, 5 = excellent.
If you have scored something 1 or 2, please tell us why in the comments box.

What did you hope to get out of this course?					
Were your expectations met?			**Yes** ☐	**No** ☐	
If not, please tell us why?					
What was your level of knowledge and skill on this subject:	1= very poor, 2 = poor, 3 = average, 4 = good, 5 = excellent				
	1	***2***	***3***	***4***	***5***
BEFORE this course					
AFTER this course					
How will course change the way you work?					

Course Content	1= very poor, 2 = poor, 3 = average, 4 = good, 5 = excellent				
	1	2	3	4	5
The relevance of the course to my actual work is					
Learning objectives were stated at the beginning of the course					
Which parts did you find most useful?					
Which parts of the course did you find least useful?					
Should any topics during the day be given MORE time?					
Should any topics during the day be given LESS time / left out?					

PLEASE COMPLETE BOTH SIDES

What information and / or practical ideas from this training will you be sharing with your colleagues at work?

Trainer and Training Delivery	1	2	3	4	5
The trainer's style of presentation & facilitating was					
The trainer's ability to answer questions & be approachable was					
The trainer's knowledge about the course subject was					
The training materials and visual aids during the course were					
The pacing of sessions (e.g. too fast or too slow) was					
The balance between theory and practical was					
Opportunity to discuss learning & its relevance to my work was					
Opportunity for me to participate was					
Handouts were					

Was there anything about the trainer's presentation and facilitating style that you found useful? *Please comment*

Is there anything that you would have improved your experience of the training session? *Please comment*

Overall	1	2	3	4	5
How satisfied were you overall with this training day?					
Would you recommend this training to others?	Yes ☐			No ☐	

Please use this space for any other comments or feedback you would like us to consider:

THANK YOU FOR TAKING THE TIME TO COMPLETE THE FORM. PLEASE RETURN IT TO AMY STREATER.

Appendix 3: Information sheets

Appendix 3.1: Person with dementia information sheet

SHIELD
Support at Home:
Interventions to Enhance
Life in Dementia

North East London NHS
NHS Foundation Trust

UCL

PARTICIPANT INFORMATION SHEET

Evaluation and Comparison of the Effectiveness of Staff Training in Maintenance Cognitive Stimulation Therapy (CST)

Invitation to participate in a research study
You are being invited to take part in a research study as part of a PhD project and the Support at Home Interventions to Enhance Life in Dementia (SHIELD) programme. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this information sheet.

What is the purpose of the study?
In recent years, cognitive stimulation therapy (CST) groups have shown to be an enjoyable and beneficial therapy for people with memory problems. The purpose of this project is to determine whether CST and Maintenance CST are effective in improving cognition and quality of life for the person with memory problems.

What happens in a cognitive stimulation therapy (CST) group?
CST groups are a 14 session programme, twice a week for seven weeks. The programme can also be run once weekly for fourteen weeks. Maintenance CST is a further 24 sessions of once weekly sessions. In total the groups should run for 31 weeks or 38 weeks, dependent on how the programme is run. The idea is to keep the mind active through multi-sensory enjoyable activities, undertaken as a structured programme facilitated by experienced and trained staff that will look after the group. Sessions include discussion of current affairs, food, sounds, physical games, number games and word games amongst others.

Why have I been chosen?
You have been invited to take part because you have at some point had a memory assessment, which makes you eligible to take part in the groups. Each CST group may include 5 to 8 people. By carrying out a measure of cognition and quality of life we are able to determine if the CST and maintenance CST groups are effective in practice.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?
If you decide to take part, your participation in the study will last for a time period of about 31 or 38 weeks. Following discussion of any questions you may have with staff, a researcher, and signing the consent form, **all participants** will be asked to:

1. Meet with a staff member and/or a member of the research team to complete a cognition and quality of life questionnaires, lasting between 10-20 minutes. The time stated to complete the interviews and questionnaires is an estimate; you may take as many breaks as you want or feel necessary, and even complete the process over two sessions if preferred.

2. To repeat these questionnaires with the staff member and/or researcher at 7 and 31 weeks or 14 and 38 weeks.

3. Attempt to attend all the sessions offered to them, unless circumstances exclude you from doing so.

Usually, the staff member and/or researcher will meet you where the sessions will be run, but will be happy to meet you elsewhere if you would prefer.

All participants entering the trial will be asked to attend twice a week for seven weeks or once a week for fourteen weeks for the CST group, and Maintenance CST groups once a week for 24 weeks. They will include up to eight people and each session will last for about an hour.

What do I have to do?
Taking part in the study does not involve any lifestyle restrictions or changes. You can carry on your everyday activities as normal while participating in the study. All we ask is that you keep your appointments with us during the time that you are taking part.

What are the possible disadvantages and risks of taking part?
CST involves participating in a group programme that aims to be stimulating and enjoyable. Sessions involve discussing themes such as food, childhood and current affairs and the level of risk in taking part is therefore minimal. If you feel uncomfortable or distressed while taking part in a group, facilitators will be able to give additional one to one support if this is needed.

What are the possible benefits of taking part?
If you decide to take part, and are involved in the CST groups we hope that this may be of some help to you, and previous group members have indeed reported that they have enjoyed the experience greatly. The information we obtain from this study may help us to understand the level of training required to give people with memory problems the best chance of receiving optimum care.

Will my taking part in the study be kept confidential?
All information that is collected about you during the course of the study will be kept strictly confidential. All data is stored without any identifying details under secure conditions.

What will happen if I don't want to carry on with the study?
You will be free to withdraw from the study at any time, without giving a reason. Withdrawing from the study will not affect the standard of care you receive. We will need to use any data collected in the study, up to the point of withdrawal.

What if something goes wrong?
If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for your legal costs.

Regardless of this, if you wish to make a complaint about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints procedures should be available to you. If you are unhappy or dissatisfied about any aspect of your participation, we would ask you to tell us about this in the first instance, so that we can try to resolve any concerns and find a solution.

Who is organising and funding the research?
The research is funded by the Department of Health, National Institute for Health Research Programme. This funding covers the running costs of the research project and is led by Professor Martin Orrell, who is an Old Age Consultant at North East London Foundation NHS Trust and a Professor of Mental Health and Ageing at University College London.

What will happen to the results of the research?
The results will be published by the Department of Health, and in relevant health journals. No participants will be identified in any publication arising from the study, without their written consent. We will make arrangements for participants to be informed of the progress of the research and the results through newsletters and local meetings.

Who has reviewed the study?
All NHS research is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well being and dignity.

Who can I contact for further information?
For more information about this research, please contact:

Amy Streater
North East London Foundation Trust,
R&D, 1st Floor.
Maggie Lilley Suite,
Goodmayes Hospital,
Ilford,
Essex,
IG3 8XJ

Phone: 0300 555 1200ex 4478
Email: a.streater@ucl.ac.uk

Or if you have any complaints about this study please contact:

Fiona Horton, R&D Administrator
R& D Department NELFT
Goodmayes Hospital, Maggie Lilley Suite
Barley Lane
Ilford
Essex,
IG3 8XJ

Phone: 0300 555 1200 ex 4485
Email: fiona.horton@nelft.nhs.uk

Thank you for considering taking part in this research study.

Appendix 3.2: Staff member information sheet (STANDOUT)

SHIELD
Support at Home:
Interventions to Enhance
Life in Dementia

North East London NHS
NHS Foundation Trust

UCL

STAFF INFORMATION SHEET

Evaluation and Comparison of the Effectiveness of Staff Training in Maintenance Cognitive Stimulation Therapy (CST)

Invitation to participate in a research study
You are being invited to take part in a research study, as part of a PhD project and the Support at Home Interventions to Enhance Life in Dementia (SHIELD) programme. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this information sheet.

What is the purpose of the study?
In recent years, cognitive stimulation therapy (CST) groups have shown to be an enjoyable and beneficial therapy for people with memory problems. This project might show the effectiveness of staff training and its level of implementation in the workplace.

What does the training involve?
The one day training course will be delivered by Dr Aimee Spector, Dr Helen Donovan or a member of the research team who have experience in the area of CST. After attending the training day you will receive the CST and Maintenance CST manuals and DVD.

What happens in a cognitive stimulation therapy (CST) group?
CST groups are a 14 session programme, twice a week for seven weeks. Maintenance CST is a further 24 sessions of once weekly sessions. In total the groups should run for 31 weeks. The activities aim to be multi-sensory and cognitively stimulating as well as enjoyable. The idea is to keep the mind active through enjoyable activities, undertaken as a structured programme facilitated by trained staff that will run and look after the group. Sessions include discussion of current affairs, food, sounds, physical games, number games and word games among others.

What does the outreach support consist of?
The outreach support will be offered to half of the staff members that enter in to the trial. This will be decided by random allocation to either of the two groups, so there will be a 50% chance of receiving the additional support. If your site is chosen to receive the outreach support it will consist of local supervision from a member of the

research team, online forum and email support. Which you will be able to access as much as you feel is necessary.

Why have I been chosen?
You have been invited to take part because you work directly with people with dementia. We need a large number of staff to help us evaluate staff training – 240 in total. It is expected that there are between 5 – 8 suitable people with dementia in your place of work that would benefit from taking part in CST groups and be available for the duration of the groups (31 weeks).

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will suffer no adverse effect.

What will happen to me if I take part?
This study is a randomised trial. We need to establish the additional benefits of staff training and outreach support, and so we need to compare any changes experienced by staff receiving varying levels of external support. The fairest way of doing this is to select people for the group by chance; everyone agreeing to take part will have a 50:50 chance of being offered additional outreach support. The decision is made by an independent computer, which will not have any identifying information about you or the person with dementia.

If you decide to take part, your participation in the study will last for a time period of about 12 months. Following discussion of any questions you may have with a researcher, and signing the consent form, **all participants** will be asked to:

1. Complete a questionnaire on-line, lasting between 30-40 minutes. The time stated to complete the interviews and questionnaires is an estimate.

2. To repeat these questionnaires online at 6 and 12 months.

3. To identify between 5-8 people with dementia that fit the inclusion criteria stated for the trial.

4. If you are randomised to receive outreach support, make use of the options that are available to you.

Additional support will be offered by a member of the research team completing the staff measures online, if and when necessary.

All staff members entering the trial will be asked to run the CST groups twice weekly for seven weeks and Maintenance CST groups, once weekly for a further 24 weeks. The group will include the five to eight people with dementia identified by you, and with the help of the research team in necessary, and each session will last for about an hour.

Focus groups
You may be asked to participate in focus groups with other staff members relating to CST. The purpose of the focus groups is to get an in depth understanding of any issues faced when running CST groups and peoples personal experience when running them, as well as peoples experiences of accessing the outreach support options available to them.

What do I have to do?
Taking part in the study does not involve any lifestyle restrictions or changes. You can carry on your everyday activities as normal while participating in the study. All we ask is that you complete the questionnaires when needed.

What are the possible disadvantages and risks of taking part?
There are no documented disadvantages to running CST groups, and is a enjoyable and beneficial experience for everyone involved. CST involves the person with dementia participating in a group programme that aims to be stimulating and enjoyable. Sessions involve discussing themes such as food, childhood and current affairs and the level of risk in taking part is therefore minimal. If the participant feels uncomfortable or distressed while taking part in a group, staff members facilitating the group will be expected to offer the individual additional support.

What are the possible benefits of taking part?
If you decide to take part, and are involved in the CST groups we hope that this may be of some help to you, both personally and professionally. Everyone will be offered training in CST, which is recommended by the NICE guidelines (2006) for people with mild to moderate dementia to participate in. Everyone will also be given additional working materials; CST and Maintenance CST manual and DVD. So there will be every opportunity to continue running the groups once the research has finished. The information we obtain from this study may help us to understand the level of training required to give people with memory problems the best chance of receiving optimum care.

Will my taking part in the study be kept confidential?
All information collected from you during the course of the study will be kept strictly confidential. All data is stored without any identifying details under secure conditions.

What will happen if I don't want to carry on with the study?
You will be free to withdraw from the study at any time, without giving a reason. Withdrawing from the study will not affect your work position in any way. We will need to use any data collected in the study, up to the point of withdrawal.

What if something goes wrong?
If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for your legal costs.

Regardless of this, if you wish to make a complaint about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints procedures should be available to you. If you are unhappy or dissatisfied about any aspect of your participation, we would ask you to tell us about this in the first instance, so that we can try to resolve any concerns and find a solution.

Who is organising and funding the research?
The research is funded by the Department of Health, National Institute for Health Research Programme. This funding covers the running costs of the research project and is led by Professor Martin Orrell, who is an Old Age Consultant at North East London Foundation NHS Trust and a Professor of Mental Health and Ageing at University College London.

What will happen to the results of the research?
The results will be published by the Department of Health, and in relevant health journals. No participants will be identified in any publication arising from the study, without their written consent. We will make arrangements for participants to be informed of the progress of the research and the results through newsletters and local meetings.

Who has reviewed the study?
All NHS research is looked at by an independent Research Ethics Committee to protect your safety, rights, well being and dignity.

Who can I contact for further information?
For more information about this research, please contact:

Amy Streater
North East London Foundation Trust,
R&D, 1st Floor Maggie Lilley Suite
Goodmayes Hospital,
Ilford,
Essex,
IG3 8XJ

Phone: 0844 6001200 ex 4478 email: a.streater@ucl.ac.uk

Or if you have any complaints about this study please contact:

Fiona Horton, R&D Administrator
R& D Department NELFT
Goodmayes Hospital, Maggie Lilley Suite
Barley Lane
Ilford Essex, IG3 8YB

Phone: 0844 600 1200 4485 email: fiona.horton@nelft.nhs.uk

Thank you for considering taking part in this research study.

Appendix 3.3: Staff information sheet (MONOU)

SHIELD
Support at Home:
Interventions to Enhance
Life in Dementia

North East London NHS
NHS Foundation Trust

UCL

STAFF INFORMATION SHEET

Evaluation and Comparison of the Effectiveness of Staff Training in Maintenance Cognitive Stimulation Therapy (CST)

Invitation to participate in a research study
You are being invited to take part in a research study, as part of a PhD project and the Support at Home Interventions to Enhance Life in Dementia (SHIELD) programme. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this information sheet.

What is the purpose of the study?
In recent years, cognitive stimulation therapy (CST) groups have shown to be an enjoyable and beneficial therapy for people with memory problems. This project might show the effectiveness of staff training and its level of implementation in the workplace.

What does the training involve?
You will receive the CST and Maintenance CST manuals and DVD as well as the opportunity to receive outreach support.

What happens in a cognitive stimulation therapy (CST) group?
CST groups are held as a 14 session programme, twice a week for seven weeks. The Maintenance CST is a further 24 sessions of once weekly sessions. In total the groups should run for 31 weeks. The activities aim to be multi-sensory and cognitively stimulating as well as enjoyable. The idea is to keep the mind active through enjoyable activities, undertaken as a structured programme facilitated by trained staff that will run and look after the group. Sessions include discussion of current affairs, food, sounds, physical games, number games and word games among others.

What does the outreach support consist of?
The outreach support will be offered to half of the staff members that enter in to the trial. This will be decided by random allocation to either of the two groups, so there will be a 50% chance of receiving the additional support. If your site is chosen to receive the outreach support it will consist of local supervision from a member of the research team, online forum and email support. Which you will be able to access as much as you feel is necessary.

Why have I been chosen?
You have been invited to take part because you work directly with people with dementia. We need a large number of staff to help us evaluate staff training – 240 in total. It is expected that there are between 5 – 8 suitable people with dementia in your place of work that would benefit from taking part in CST groups and be available for the duration of the groups (31 weeks).

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will suffer no adverse effect.

What will happen to me if I take part?
We need to establish the additional benefits of staff training and outreach support, and so we need to compare any changes experienced by staff receiving varying levels of external support. The fairest way of doing this is to select people for the group by chance; everyone agreeing to take part will have a 50:50 chance of being offered additional outreach support. The decision is made by an independent computer, which will not have any identifying information about you or the person with dementia.

If you decide to take part, your participation in the study will last for a time period of about 12 months. Following discussion of any questions you may have with a researcher, and signing the consent form, **all participants** will be asked to:

1. Complete a questionnaire on-line, lasting between 30-40 minutes. The time stated to complete the interviews and questionnaires is an estimate.

2. To repeat these questionnaires online at 6 and 12 months.

3. To identify between 5-8 people with dementia that will be suitable for CST groups.

4. If you are randomised to receive outreach support, make use of the options that are available to you.

Additional support will be offered by a member of the research team completing the staff measures online, if and when necessary.

All staff members entering the trial will be asked to run the CST groups twice weekly for seven weeks and Maintenance CST groups, once weekly for a further 24 weeks. The group will include the five to eight people with dementia identified by you, and with the help of the research team in necessary, and each session will last for about an hour.

Focus groups
You may be asked to participate in focus groups with other staff members relating to CST. The purpose of the focus groups is to get an in depth understanding of any issues faced when running CST groups and peoples personal experience when running them, as well as peoples experiences of accessing the outreach support options available to them.

What do I have to do?
Taking part in the study does not involve any lifestyle restrictions or changes. You can carry on your everyday activities as normal while participating in the study. All we ask is that you complete the questionnaires when needed.

What are the possible disadvantages and risks of taking part?
There are no documented disadvantages to running CST groups, and is an enjoyable and beneficial experience for everyone involved. CST involves the person with dementia participating in a group programme that aims to be stimulating and enjoyable. Sessions involve discussing themes such as food, childhood and current affairs and the level of risk in taking part is therefore minimal. If the participant feels uncomfortable or distressed while taking part in a group, staff members facilitating the group will be expected to offer the individual additional support.

What are the possible benefits of taking part?
If you decide to take part, and are involved in the CST groups we hope that this may be of some help to you, both personally and professionally. CST is recommended by the NICE guidelines (2006) for people with mild to moderate dementia to participate in. Everyone will also be given additional working materials; CST and Maintenance CST manual and DVD. So there will be every opportunity to continue running the groups once the research has finished. The information we obtain from this study may help us to understand the level of training required to give people with memory problems the best chance of receiving optimum care.

Will my taking part in the study be kept confidential?
All information collected from you during the course of the study will be kept strictly confidential. All data is stored without any identifying details under secure conditions.

What will happen if I don't want to carry on with the study?
You will be free to withdraw from the study at any time, without giving a reason. Withdrawing from the study will not affect your work position in any way. We will need to use any data collected in the study, up to the point of withdrawal.

What if something goes wrong?
If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for your legal costs.

Regardless of this, if you wish to make a complaint about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints procedures should be available to you. If you are unhappy or dissatisfied about any aspect of your participation, we would ask you to tell us about this in the first instance, so that we can try to resolve any concerns and find a solution.

Who is organising and funding the research?
The research is funded by the Department of Health, National Institute for Health Research Programme. This funding covers the running costs of the research project and is led by Professor Martin Orrell, who is an Old Age Consultant at North East London Foundation NHS Trust and a Professor of Mental Health and Ageing at University College London.

What will happen to the results of the research?
The results will be published by the Department of Health, and in relevant health journals. No participants will be identified in any publication arising from the study, without their written consent. We will make arrangements for participants to be informed of the progress of the research and the results through newsletters and local meetings.

Who has reviewed the study?
All NHS research is looked at by an independent Research Ethics Committee to protect your safety, rights, well being and dignity.

Who can I contact for further information?
For more information about this research, please contact:

Amy Streater
North East London Foundation Trust,
R&D, 1st Floor Maggie Lilley Suite
Goodmayes Hospital,
Ilford, Essex, IG3 8XJ

Phone: 0844 6001200 ex 4478 Email: shield@nelft.nhs.uk

Appendix 3.4: Manager information sheet

SHIELD
Support at Home:
Interventions to Enhance
Life in Dementia

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MANAGEMENT INFORMATION SHEET

Evaluation and Comparison of the Effectiveness of Staff Training in Maintenance Cognitive Stimulation Therapy (CST)

Invitation to participate in a research study
You are being invited to take part in a research study, as part of a PhD project and the Support at Home Interventions to Enhance Life in Dementia (SHIELD) programme'. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this information sheet.

What is the purpose of the study?
In recent years, cognitive stimulation therapy (CST) groups have shown to be an enjoyable and beneficial therapy for people with memory problems. This project might show the effectiveness of staff training and its level of implementation in the workplace.

What does the training involve?
The one day training course is run by Dr Aimee Spector, an expert in the field of CST. It is expected that 3 staff members from your establishment will attend the training day, they will then receive the CST and Maintenance CST manuals and DVD. It is expected that the training day and additional learning material will equip your staff with the skills necessary to run CST and Maintenance CST groups.

What happens in a cognitive stimulation therapy (CST) group?
CST groups are a 14 session programme, twice a week for seven weeks. Maintenance CST is a further 24 sessions of once weekly sessions. In total the groups should run for 31 weeks. The activities aim to be multi-sensory and cognitively stimulating as well as enjoyable. The idea is to keep the mind active through enjoyable activities, undertaken as a structured programme facilitated by trained staff that will run and look after the group. Sessions include discussion of current affairs, food, sounds, physical games, number games and word games among others.

What does the outreach support consist of?
The outreach support will be offered to half of the staff members that enter in to the trial. This will be decided by random allocation to either of the two groups, so there will be a 50% chance of receiving the additional support. If your site is chosen to receive the outreach support it will consist of local supervision from a member of the research team, online forum and email support.

Why have I been chosen?
You have been invited to take part because you workplace has direct contact with people with dementia. We need a large number of staff to help us evaluate staff training – 240 in total, who would be expected to stay in your employment for the 12 month period of the research project. It is expected that there are between 5 – 8 suitable people with dementia in your place of work that would benefit from taking part in CST groups and be available for the duration of the groups (8 months).

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will suffer no adverse effect.

What will happen to me if I take part?
This study is a randomised trial. We need to establish the additional benefits of staff training and outreach support, and so we need to compare any changes experienced by staff receiving varying levels of external support. The fairest way of doing this is to select people for the group by chance; everyone agreeing to take part will have a 50:50 chance of being offered additional outreach support. The decision is made by an independent computer, which will not have any identifying information about you or the people with dementia.

If you decide to take part, your participation in the study will last for a time period of about 12 months. Following discussion of any questions you may have with a researcher, and signing the consent form, **all management** will be asked to:

1. Allow the members of staff online access to the questionnaires at the beginning of the trial, and 6 and 12 months thereafter.

2. To assist the staff members to identify between 5-8 people with dementia.

3. Allow the staff members who have attended training two hours per week for the first seven weeks to run CST groups, and one hour per week for the following 24 weeks to run Maintenance CST groups.

4. To attempt to provide the staff with the necessary tools and materials to run the CST and Maintenance CST groups.

Additional support will be offered by a member of the research team to complete the staff measures online, if and when necessary.

All participants entering the trial will be asked to run the CST groups twice weekly for seven weeks and Maintenance CST groups, once weekly for a further 24 weeks. The group will include the five to eight people with dementia identified by you and your staff and each session will last for about an hour.

Focus groups
You may be asked to participate in focus groups with other staff members relating to CST. The purpose of the focus groups is to get an in depth understanding of any issues faced when running CST groups and peoples personal experience when running them, as well as peoples experiences of accessing the outreach support options available to them.

What do I have to do?
Taking part in the study does not involve any lifestyle restrictions or changes. You can carry on your everyday activities as normal while participating in the study. All we ask is that you allow the staff members to complete the questionnaires when necessary and provide them with the time and tools to run the CST and Maintenance CST groups.

What are the possible disadvantages and risks of taking part?
There are no documented disadvantages to running CST groups, and is an enjoyable and beneficial experience for everyone involved. CST involves the person with dementia participating in a group programme that aims to be stimulating and enjoyable. Sessions involve discussing themes such as food, childhood and current affairs and the level of risk in taking part is therefore minimal. If the participant feels uncomfortable or distressed while taking part in a group, staff members facilitating the group will be expected to offer the individual additional support.

What are the possible benefits of taking part?
If you decide to take part, and are involved in the CST groups we hope that this may be of some help to you, both personally and professionally. Everyone will be offered training in CST, which is recommended by the NICE guidelines (2006) for people with mild to moderate dementia to participate in. Everyone will also be given additional working materials: two manuals and a DVD. So, there will be every opportunity to continue running the groups once the research has finished. The information we obtain from this study may help us to understand the level of training required to give people with memory problems the best chance of receiving an optimum level of care.

Will my taking part in the study be kept confidential?
All information collected from you during the course of the study will be kept strictly confidential. All data is stored without any identifying details under secure conditions.

What will happen if I don't want to carry on with the study?

You will be free to withdraw from the study at any time, without giving a reason. Withdrawing from the study will not affect your work position in any way. We will need to use any data collected in the study, up to the point of withdrawal.

What if something goes wrong?
If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for your legal costs.

Regardless of this, if you wish to make a complaint about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints procedures should be available to you. If you are unhappy or dissatisfied about any aspect of your participation, we would ask you to tell us about this in the first instance, so that we can try to resolve any concerns and find a solution.

Who is organising and funding the research?
The research is funded by the Department of Health, National Institute for Health Research Programme. This funding covers the running costs of the research project and is led by Professor Martin Orrell, who is an Old Age Consultant at North East London Foundation NHS Trust and a Professor of Mental Health and Ageing at University College London.

What will happen to the results of the research?
The results will be published by the Department of Health, and in relevant health journals. No participants will be identified in any publication arising from the study, without their written consent. We will make arrangements for participants to be informed of the progress of the research and the results through newsletters and local meetings.

Who has reviewed the study?
All NHS research is looked at by an independent Research Ethics Committee to protect your safety, rights, well being and dignity.

Who can I contact for further information?
For more information about this research, please contact:

Amy Streater
North East London Foundation Trust,
R&D, 1st Floor
Maggie Lilley Suite
Goodmayes Hospital,
Ilford,
Essex,
IG3 8XJ

Phone: 0844 6001200 ex 4491 email: a.streater@ucl.ac.uk

Or if you have any complaints about this study please contact:

Fiona Horton R&D Administrator
R& D Department NELFT
Goodmayes Hospital, Maggie Lilley Suite
Barley Lane
Ilford Essex, IG3 8YB

Phone: 0844 600 1200 4485 email: fiona.horton@nelft.nhs.uk

Thank you for considering taking part in this research study.

Appendix 4: Screening and consent forms

Appendix 4.1: Staff member consent form

SHIELD
Support at Home:
Interventions to Enhance
Life in Dementia

North East London NHS
NHS Foundation Trust

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Staff Consent Form
Participant Identification Number for this trial _____

Evaluation and Comparison of the Effectiveness of Staff Training in Maintenance Cognitive Stimulation Therapy (CST)

	Please Initial Boxes
1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, with out the medical care or legal rights of myself or my relative being affected.	☐
3. I understand that sections of any of the person with dementia medical notes may be looked at by individuals involved in the trial or from regulatory authorities where it is relevant to taking part in this research.	☐
4. I have been consulted regarding the participation of the person with dementia, as required by the Mental Capacity Act, and I believe they would wish to take part / continue to take part the study.	☐
5. I understand that all information given by me or about me or the person with dementia will be treated as confidential by the research team.	☐
6. I understand that I may be asked to participate in a focus group, whilst I am participating in the trial, relating to my experiences of CST.	☐
7. I agree to take part in the above study.	☐

Name of staff member Date Signature

_____ _____ _____

Name of site _____

Researcher Date Signature

_____ _____ _____

4.1 Staff consent form.doc Page 1 of 1
Professor Martin Orrell m.orrell@ucl.ac.uk Tel:0207 6799452
RP-PG-0606-1083 03/05/2011 ISRCTN28793457
East London 3 Research Ethics Committee REC number 11/LO/0059

Appendix 4.2: Manager consent form

SHIELD
Support at Home:
Interventions to Enhance
Life in Dementia

North East London NHS
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Kent and Medway NHS
NHS and Social Care Partnership Trust

Ms Alison Culverwell
Consultant Clinical Psychologist and Head of Psychological Services (Older People)
Gregory House, St Martin's Hospital
Littlebourne Road
Canterbury CT1 1TD
Telephone: 01227 865846

Management Consent Form
Participant Identification Number for this trial _____

Evaluation and Comparison of the Effectiveness of Staff Training in Maintenance Cognitive Stimulation Therapy (CST)

	Please Initial Boxes
1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, with out the medical care or legal rights of myself or my relative being affected.	☐
3. I understand that sections of any of the person with dementia medical notes may be looked at by individuals involved in the trial or from regulatory authorities where it is relevant to taking part in this research.	☐
4. I have been consulted regarding the participation of the person with dementia, as required by the Mental Capacity Act, and I believe they would wish to take part / continue to take part the study.	☐
5. I understand that all information given by me or about me or the person with dementia will be treated as confidential by the research team.	☐
6. I agree to take part in the above study.	☐

Name of manager **Date** **Signature**

_____ _____ _____

Name of site _____

Researcher **Date** **Signature**

_____ _____ _____

Appendix 4.3: Person with dementia screening checklist

SHIELD
Support at Home: Interventions to Enhance Life in Dementia

North East London NHS
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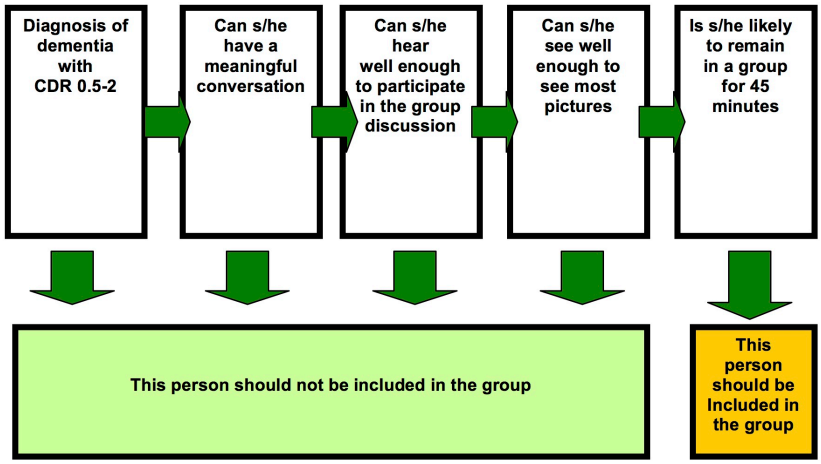
Screening and Inclusion criteria for MCST implementation in practice

1. Screening:
Instructions
For a person with dementia to participate in the research trial; Maintenance Cognitive Stimulation Therapy (CST) implementation in practice they are required to meet the inclusion criteria set below. The first diagram shows the inclusion criteria required for a person with dementia to be able to participate in CST groups. These are guidelines that are useful in determining the suitability of the group members. If a person does not fulfil any of the inclusion criteria please mark accordingly.



Inclusion criteria meet: **Yes** **No**

2. National Institute of Social Work (NISW):
Instructions

SHIELD
Support at Home:
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Does the person have noticeable problems in:

	Yes	No
Remembering recent events?	☐	☐
Working out how to do some basic everyday tasks such as dressing, making tea, going to the toilet?	☐	☐
Knowing the time?	☐	☐
Knowing where he or she is?	☐	☐
Correctly naming persons seen regularly?	☐	☐
Keeping in touch with a conversation?	☐	☐

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NISW Criteria:	**Yes**	**No**
CDR Score:	**Yes**	**No**
Included in trial:	**Yes**	**No**
If YES →	**CRF Number:**	

Appendix 4.4: Person with dementia consent form

SHIELD
Support at Home:
Interventions to Enhance
Life in Dementia

North East London NHS
NHS Foundation Trust

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Participant Consent Form
Participant Identification Number for this trial _____

Evaluation and Comparison of the Effectiveness of Staff Training in Maintenance Cognitive Stimulation Therapy (CST)

	Please Initial Boxes
1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, with out the medical care or legal rights of myself or my relative being affected.	☐
3. I understand that sections of any of my medical notes may be looked at by individuals involved in the trial or from regulatory authorities where it is relevant to my taking part in this research. I give my permission for these individuals to have access to my records.	☐
4. I understand that all information given by me or about me will be treated as confidential by the research team.	☐
5. I give permission for my GP to be informed of my participation in the study.	☐
6. I agree to take part in the above study.	☐

Name of participant	**Date**	**Signature**
_____	_____	_____

Name of site _____

Staff member / Researcher	**Date**	**Signature**
_____	_____	_____

Appendix 5: Assessment measures and interview schedule

Appendix 5.1: Minnesota Satisfaction Questionnaire (MSQ)

Removed due to copyright issues

Appendix 5.2: Approaches to Dementia Questionnaire (ADQ)

Removed due to copyright issues

Appendix 5.3: Dementia Knowledge – 20 (DK-20)

Removed due to copyright issues

Appendix 5.4: Sense of competence in dementia care staff scale (SCIDS)

Removed due to copyright issues

Appendix 5.5: Brief Learning Transfer System Inventory (Brief LTSI)

Removed due to copyright issues

Appendix 5.6: Barriers to Change Questionnaire (BARCQ)

Removed due to copyright issues

Appendix 5.7: Controllability Belief Scale (CBS)

Removed due to copyright issue

Appendix 5.8: Mini Mental State Examination (MMSE)

Removed due to copyright issues

Appendix 5.9: Quality of Life – Alzheimer's Disease (QOL-AD)

Removed due to copyright issues

Appendix 5.10: Focus group interview schedule

Maintenance CST Focus Group Topic Guide – Staff

Aims of the group

- To elicit views and experiences of the maintenance CST programme from staff members following delivery of the training programme and implementing CST in their workplace.
- To elicit views relating to the outreach support options and uptake of this.
- To elicit view on the use of attendance and adherence booklet and usefulness when running programme
- To identify any aspects that may require amending to increase maintenance CST suitability for use in practice.

Introduction by Moderator:

- Welcome participants and thank them for coming.
- Introduce self and colleague.
- Remind participants that the purpose of the session is to gain participants views on their experience in delivery of the maintenance CST programme and outreach support options. The participants are here to share their experiences and views on the topic.
- The results will be used to inform the facilitation and additional support necessary to implement the maintenance CST programme in practice.
- Explain what will happen during the session:
    - Moderator will ask some questions to start a discussion
    - The co-facilitator will write some notes based on observation – and will summarise the main points at the end of the session
    - The discussion will be tape recorded because it is not possible to write everything down and it is important to be accurate and not 'lose' any valuable information. The recording will be transcribed (typed up) and then deleted.
    - Remind and reassure participants that personal details and information collected from this discussion will remain confidential to the research team and no one will be identifiable within any report or publication that results.
- Confirm the time due to finish
- Explain the 'ground rules':
    - Speak freely
    - Only one person to speak at a time
    - Feel free to speak to each other, not just the moderator

- There are no right or wrong answers and can say positive or negative things
- Participants do not all have to agree but must respect others' opinions even if they differ from their own
- Please turn all mobile devices off during the session
- What is said during the session remains confidential and must not be discussed outside of the group

Introduction text

'Good morning and welcome to our session. Thanks for taking the time to talk to us about the maintenance CST programme and outreach support as part of the 'maintenance CST implementation in practice' study. We want to know what your opinion of running the CST and maintenance CST programme is, any parts you disliked / enjoyed and difficulties you faced, the outreach support options, and how they might be improved.

You were invited because you participated in the 'maintenance CST implementation in practice' study so you are familiar with the programme and outreach support options that were on offer during your time in the research.

There are no right or wrong answers, just difference of opinion. Please feel free to share your point of view even if it differs from others. Please keep in mind that we are just as interested in negative feedback as well as the positive, as all feedback is important and useful in developing the programme further.

As you might have already noticed we have a microphone and will be taping the session. This is so we do not miss anything that is being said. People often make very useful contributions during these sessions and it can be hard to write everything down fast enough. We will be on a first name basis, however no names will be used in the writing up of the report. You must be assured that you all your information will be treated with confidentiality. The comments that you provide us with will assist in considering the development of the programme further to better the chances of the uptake of CST in a variety of care settings.

Well let's begin. Although you are wearing name tags please could you go around the group, introduce yourself and tell us any hobbies!'

Views about the programme

- What do you think of the maintenance CST programme after having taken part? *Pro's and con's of programme, any differences identified from the original CST programme, probe delivery methods and frequency.*
- Do you think the therapy has a therapeutic value for the people with dementia participating in the programme?

Benefits, constraints, use of activities, feedback from family caregivers or other staff members, perceived benefits for pwd, perceived benefit for staff

- What do you believe the group facilitator skills are that are necessary to implement the programme?
  Training required, necessary guidance, additional support required.
- What level of support were you receiving during the research?
- Is there anything missing from the manuals that you think would help when running the programme?
- What aspects do you think are missing from the programme and what would you change? *Probe for concrete examples*
- How did you find the attendance and adherence booklets that were completed after each session?
  Usefulness, time taken to complete, perceived purpose of booklet
- What do you think you need in order to implement the CST and maintenance CST programme?
- Do you believe it is possible to continue the maintenance CST programme for a further 24 weeks following on from the CST programme? *Difficulties, feasibility, context.*
- What was your experience of the outreach support?
  What did you require from the outreach support? What was missing? What might you have preferred? Were there any reasons for not accessing it?
- Are there any aspects of your service, role or organisation you think will act as barriers to the implementation of the maintenance CST programme?
  Are there aspects that facilitate it?
- What part of the programme do they tend to dismiss if any (place less importance on and why).

Closing

- Is there anything else you would like to share with us?
- Of all the things we have discussed, what for you is the most important?

Thank attendees for their time and participation
Explain what will happen next: we will type up what has been said, as the main researcher I will then review these and analyse and write up the results for publication as an article in an academic journal informing implementation into practice of the maintenance CST programme and addition of outreach support.

Things to consider

Use appropriate phrases 'would you explain further', 'could you give an example' and avoid positive reinforcement.

Transcribe quickly to avoid forgetting important contributions

Role of co-facilitator

Make notes of seating arrangement of participants

Make notes of what order people are speaking.

Write down notable comments – place initial of speaker next to quote

Any observations of group members (e.g. John is withdrawn, Pat is quiet) nods, smiling, eye contact between group members

Sum up the contributions from the group members at the end then ask 'is this an adequate summary?'

Ask any questions that could have been expanded on from comments provided by the group members earlier in the session

Monitor recording equipment

Debrief with main facilitator

Incentives for participation

£20 Marks & Spencer voucher

Gifts

Positive invitation

Opportunity to share opinions

Enjoyable, convenient, and easy to find location

Involvement in important research

Appendix 6: Analysis plan and adverse event reporting

Appendix 6.1: STANDOUT and MONOU analysis plan

SHIELD maintenance CST implementation in practice analysis plan – STANDOUT & MONOU

Table of Contents

Version 5 28/06/2013

Analysis plan STANDOUT & MONOU trial

Introduction

The SHIELD maintenance Cognitive Stimulation Therapy (CST) implementation in practice trial is a randomized controlled trial looking at the effects of staff training and delivery of outreach support for CST and maintenance CST groups with dementia care staff. Potential participants are screened for eligibility before their baseline assessment. Each participant is then randomised into one of two groups, intervention (outreach support) or treatment as usual (no outreach support). The participants have 3 months to commence the CST (twice weekly for 7 weeks or once weekly for 14 weeks) programme followed on by the maintenance CST programme (once weekly for 24 weeks). Follow up assessments occur at 6 and 12 months.

The trial objectives are:

1. To conduct a randomised control trial to determine the effectiveness and long-term effects of the implementation of two different CST training approaches in practice. (A) Training day, CST and maintenance CST manual, DVD and outreach support versus (B) Training day, CST and maintenance CST manual, and DVD.
2. To carry out a qualitative evaluation using focus groups looking at the issues and experiences associated with running CST and maintenance CST groups, and receiving outreach support in a variety of dementia settings.

Primarily, assessment of efficacy will be on number of attendees to the sessions over the time frame of the CST and maintenance CST groups.

Analysis for this trial will follow the intention to treat (analysis by allocated treatment) principles [1] and follow all guidelines set out and required by the 2010 CONSORT statement [2].

Randomisation methodology.

Randomisation of the participants will be clustered by centre.

Once all participants within a centre have consented and completed the baseline assessment the centre is then randomised to one of two groups, the treatment as usual or intervention group on a 1:1 basis. Both groups will receive the training package and implement the CST and maintenance CST programme. Exceptions to this randomisation will be in the case where a person is unable to attend the training day, or completed the baseline assessment after the initial randomisation but before the centre is aware of their randomisation allocation they will be randomised by association to the same group as their place of work. A balance will be attempted to be maintained between the numbers of participants per centre allocated to the treatment as usual and the intervention group, however due to the cluster randomisation this may not always be possible.

Inclusion and Exclusion criteria

Participants will be considered suitable for full assessment and participation if they meet the following inclusion criteria:

a) Staff members' working directly for people with dementia

b) Willingness to self complete three sets of questionnaires within a year time frame (baseline, 6 month follow up, 12 month follow up)
c) Adequate written and spoken comprehension of the English language
d) Opportunity to recruit five to eight suitable people in the mild to moderate stages of dementia
e) Access to a computer and an adequate level of competency to complete questionnaires online
f) Each centre will contribute three or more staff members who will intend to run CST groups for the STANDOUT trial and at least one staff member for the MONOU trial.
g) Agreement with management to have time set aside to run CST sessions and one hour a week, set aside, for the following 24 weeks of maintenance CST groups

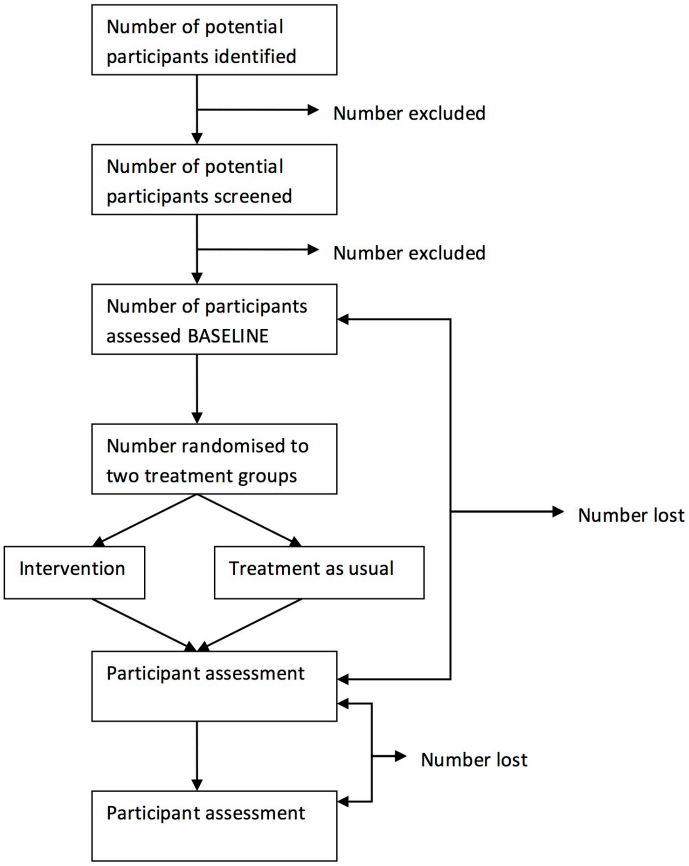
The STANDOUT trial differs from the MONOU trial in that people recruited in to the STANDOUT trial are new to CST, whereas participants recruited in to the MONOU trial have either attended the commercial CST training day or purchased the CST 'Making a difference' manual.

Blinding STANDOUT and MONOU trial

Researchers will remain blind to identifying the participant to their individually assigned identification number wherever possible. The researchers delivering the training will not be able to identify the persons identification number, unless they become unblinded by the participant. A member of the administration team will assign each individual an identification number which they will then add when completing their online assessment. If the participant can not remember their identification number this will be added at a later date by a member of the administration team and will not stop them from completing the assessment.

Full analysis will be conducted with blinded group allocations, which will only be revealed after conclusions have be drawn. Compliance analysis on the level of useage of the outreach support service will only be conducted once the full analysis has been completed this is due to the potential of once a compliance variable has been added to the dataset the trial will become unblinded.

Flowchart of participants



Hypothesis for primary outcomes

Null hypothesis for the primary outcome: There is no difference between those receiving outreach support and those that are not on number of attendees to the CST and maintenance CST sessions.

Alternate hypothesis for the primary outcome: There is a difference between those receiving outreach support and those that are not on number of attendees to the CST and maintenance CST sessions

The primary outcomes for the hypothesis testing will be the percentage of attendance to the sessions offered by the centre over the timeframe of the CST and maintenance CST programme

Attendance ('Making a difference' manual monitoring progress form)
The monitoring progress form records individual attendance level of interest, communication, enjoyment and mood of the person with dementia subjectively graded by the participant. There is also the option to record activities used and additional comments.

Sample size calculation

Working on the premise of a 15% attrition rate a sample size of 240 across the STANDOUT and MONOU trial will provide sufficient numbers for the staff training outreach support / no outreach support to estimate effect size and the feasibility of the trial. The combined sample size is necessary for an intervention of moderate power with an effect size of 0.4. This figure assumes the intra-cluster correlation, p to be 0.05.

Data management

Data has been directly entered into SurveyMonkey there are limited data checks that can be made on this data. The data will be extracted from SurveyMonkey and analysed in SPSS.

Analysis for primary outcome

The data for both the STANDOUT and MONOU trials will be analysed together taking into account the method of recruitment. This is as planned by the derivation of the sample size calculation that required 240 participants.

Demographics and baseline characteristics will be given for the whole sample, as well as being broken down by centre and trial arm. Analysis will take place using SPSS version 18. Intention to Treat analysis will be used. Regardless of whether or not the participant received the treatment they were randomised to receive they will analysed within the group they were allocated to.

Missing data

There will be three types of missing data within this dataset. Missing items within measure and missing measures at time points and missing participants.

For items missing within measure the rules for completing missing data for the relevant measure will be applied, see Table 1 Appendix 1. The missing data rules implemented for each measure are considered part of the validated tool and therefore will be used as designed in line with the original validation.

All summary scores for the measures will be calculated in line with the scoring rules established at the point of the measures validation.

Pro-rating on a 20% missing case basis will be applied, i.e. for a 5 item score if one item is missing this value will be filled with the mean of the other 3 values.

Once the measure rules have been applied there will only be missing time point data left.

We will apply a linear regression within treatment group to impute the summary scores for post randomisation time points in line with the trend seen within the centre. That is, the group line of

regression will be applied to the existing values for the participant. Imputation for baseline measurements will be made solely within the baseline data set with no reference to randomised treatment group. This will be done on a multiple imputation basis to incorporate a sensitivity analysis within the main analysis.

Scoring exceptions

During cleaning and assessment of the data quality it has become apparent that there are some discrepancies between the measures utilised and the measures referenced.

Minnesota Satisfaction Questionnaire

The paper versions of the questionnaires included the new scoring of not satisfied, slightly satisfied, satisfied, very satisfied, extremely satisfied.

The explanation of the new scoring is the neutral point (Neither) is eliminated. The two dissatisfied categories (dissatisfied and very dissatisfied) are collapsed into one (Not satisfied) and four degrees of satisfaction (slightly satisfied, satisfied, very satisfied, extremely satisfied) are provided.

The paper versions of the questionnaire have been adapted to be the old scoring options (to fall in line with the online responses).

Clinical effectiveness methods

Primary model

The primary outcome is a proportion measure or attendance at MCST programme sessions.

Total number of sessions attended = total number of sessions run x average number of people at each

Model 1. Is number of attendees at 7 or 14 weeks and 31 weeks after the initial CST programme dependent on whether the centre is allocated to the treatment group. This will take into account covariates of type of centre, delivery of sessions over 7 or 14 weeks, whether it is a specialist dementia setting and method of recruitment (STANDOUT/ MONOU).

The model fitted will be ANCOVA.

Analysis for secondary outcomes

Secondary outcomes are individual level questionnaire scores. An ANCOVA taking account of the cluster randomised design will be fitted. This will take into account that staff members are nested within care centres nested within treatment groups.

Secondary models

Model 2. The ANCOVA will be fitted with Follow up 2 as the dependent variable, centre, age, gender, qualifications, level of experience, delivery mode (7/14 weeks), type of centre, specialist dementia setting, method of recruitment

(STANDOUT/ MONOU) and baseline score will be taken as the independent variables.

Model 3. The ANCOVA will be fitted with Follow up 1 as the dependent variable, centre, age, gender, qualifications, level of experience, delivery mode (7/14 weeks), type of centre, specialist dementia setting method of recruitment (STANDOUT/ MONOU) and baseline score will be taken as the independent variables.

The above models will be fitted with the following secondary outcomes as the dependent variable (also listed in Appendix 1).

1. Approaches to Dementia Questionnaire (ADQ, Lintern & Woods., 1996)
2. Minnesota Satisfaction Questionnaire (MSQ, Weiss et al., 1967)
3. Controllability Belief Scale (CBS, Dagnan, Grant & McDonnell., 2004)
4. Sense of Competence in Dementia Care Staff (SCID-S, Schepers., 2010)
5. Brief Learning Transfer System Inventory (BLTSI, Holton, Bates & Ruona., 2000)
6. Barriers to Change Questionnaire (BARCQ, Corrigan, Kwartarini & Pramana., 1992)
7. Dementia Knowledge Questionnaire (DKQ-20, baseline and follow up 2 only) (Shanahan et al., 2012)

In total this will give at least 16 models (ignoring the subscales that the outcome measures give) in total for analysis. These models will all be considered hypothesis generating rather than hypothesis confirming.

Additional outcomes

The adverse events and withdrawal rates will be tabulated across the trial. Evidence of any differential rates between the two treatment groups will also be identified for adverse events and withdrawal rates.

Intervention compliance has been recorded by way of attendance of the programme and adherence to the key principles as developed under the maintenance CST project.

List of tables

Baseline analysis

Need to create for staff and for pwd

1. Demographic information of complete sample
    a. Borough
    b. Centre name
    c. Type of centre
    d. Specialist dementia care setting

e. Gender (Frequencies)

f. Age of staff member

g. Job title

h. Level of experience (min, max, mean, standard deviation)

i. Highest qualification (min, max, mean, standard deviation)

j. Ethnic group (Frequencies)

2. Demographics as above broken down by trial group (blinded as 1:1 allocation)
3. Demographics as above broken down by centre (geographic location)
4. Secondary measures (Min, max, Mean, Standard Deviation)

Interim analysis

Full analysis

List of figures

References

1. ICH E9 Expert Working Group. Statistical Principles for Clinical Trials: ICH Harmonized Tripartite Guideline. Statistics in Medicine 1999; 18:1905–1942.
2. CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. Schulz KF, Altman DG, Moher D for the CONSORT group. Ann Int Med 2010; 152 Epub 24 March 2010.
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Appendix 1. Outcome measures.

Outcome measure	Reference	Scoring	Subscales	Missing value rules	Thresholds
ADQ	Lintern, T & Woods, B. (1996).	Sum of all 19 items to give a total score (min 19 max 95)	Two subscales: *Hope* – items 1,2,3,4,6,8,10 & 13 *Person-centeredness* – items 5,7,9,11,12,14,15,16,17,18,19	No missing values established, however it is suggests to allow one missing value for each sub-scale and substitute with the mean value of that subscale for that participant	None.
MSQ	Weiss, D. Dawis, R. England, G. Lofquist, L. (1967)	Sum of all 100 items to give a total score (min 100 max 500). 1 = very dissatisfied 2 = dissatisfied 3 = neither 4 = satisfied 5 = very satisfied	20 subscales: *Ability utilization, Achievement, Activity, Advancement, Authority, Company policies and practices, Compensation, Co-workers, Creativity, Independence, Moral values, Recognition, Responsibility, Security, Social service, Social status, Supervision-human relations, Supervision-technical, variety & Working conditions. General satisfaction is optional.*		75% or above (375 or more) represents a high degree of satisfaction, 25% or lower (125 or less) represents a low level of satisfaction and 26-74% indicates average satisfaction
CBS	Dagnan, D. Grant, F. McDonnell, A. (2004).	15 item questionnaire (min 15 max 75)	2 subscales: Perception of high control – items 1, 3, 4, 6, 7, 8, 10, 11, 12, 14.	None.	None.

				Perception of low control – items 2, 5, 9, 13, 15.		
SCID-S	Schepers, A. (2010).	17 item questionnaire 4 point Likert scale (min 17 max 68)		Four subscales: *professionalism, building relationships, care challenges and sustaining personhood*	None.	None.
BLTSI	Holton, E. Bates, R. & Ruona, W. (2000).	16 item short form questionnaire. All of the items use five-point Likert-type scales from 1 (strongly disagree) to 5 (strongly agree) (min 16 max 80)		*Learner readiness, Motivation to transfer, Positive personal outcomes, Negative personal outcomes, Personal capacity for transfer, Peer support, Supervisor support, Supervisor sanctions, Perceived content validity, Transfer design, Opportunity to use, Transfer effort-performance expectations, Performance-outcomes expectations, resistance-openness to change, Performance self-efficacy, Performance coaching*	None.	None.
BARCQ	Corrigan, P. Kwartarini, W. & Pramana, W. (1992).	19 item questionnaire not a barrier at all (0), a very slight barrier (1), a small barrier (2), a modest barrier (3), a large barrier (4) and an insurmountable barrier (5). (min 0 max 95)		5 constructs; *Institutional constraints, Insufficient collegial support, Philosophical opposition, Client dissatisfaction, Collateral interference*	None.	None.
DKQ-20	Shanahan, N. Schepers, A. Spector,	Summation of the 20 items to give a total		Dementia core knowledge (11 items, 2 sub-domains) – *general*	None	None

	A. Orrell, M., (2012).	score (min 0 max 20)	*knowledge(8)* & *behavioural and psychological symptoms of dementia (3)* Dementia care knowledge (9 items, 6 sub-domains) – *person-centeredness, communication, psychosocial interventions/activities, managing challenging behaviour, risk abuse prevention, consent and decision making.*		

Appendix 6.2: Observational study analysis plan

SHIELD maintenance CST implementation in practice analysis plan – Observational Study

Table of Contents

Version 5 28/06/2013

Introduction

The SHIELD maintenance Cognitive Stimulation Therapy (CST) implementation in practice trial is a randomized controlled trial looking at the effects of staff training and delivery of outreach support for cognitive stimulation therapy (CST) and maintenance CST groups with dementia care staff. An additional element to this trial is an observational study of people with dementia including minimal outcome measures to determine if CST is as effective in practice as previously conducted research (Spector et al., 2001, Orrell et al., 2005, Aguirre et al., 2011). Potential participants are screened for eligibility before their baseline assessment. No randomisation occurs as all people with dementia are in receipt of the CST and maintenance CST programme. The implementation of the programme is decided on by the centre and is twice weekly for 7 weeks or once weekly for 14 weeks. The maintenance programme is once weekly for a further 24 weeks. Follow up assessments occur after the completion of the CST programme (7/31 or 14/38 weeks) and after the maintenance CST (31/31 or 38/38 weeks) i.e. during the intervention and after completing the programme.

The trial objectives are:-

1. To conduct an observational study to determine the effectiveness and long term effects (cognition and quality of life) of CST and maintenance CST in a variety of care settings.

Primarily, assessment of efficacy will be on the severity of dementia using the Mini Mental State Examination (Folstein et al., 1975) and the participants quality of life using QoL-AD (Longsdon et al., 2002).

Analysis for this trial will follow the intention to treat principles [1] and follow all guidelines set out and required by the 2010 CONSORT statement [2].

Randomisation methodology.

No randomisation will occur for the people with dementia as all will be in receipt of the CST and maintenance CST programme.

Inclusion and Exclusion criteria

Participants will be considered suitable for full assessment and participation if they meet the following inclusion criteria.

INCLUSION CRITERIA

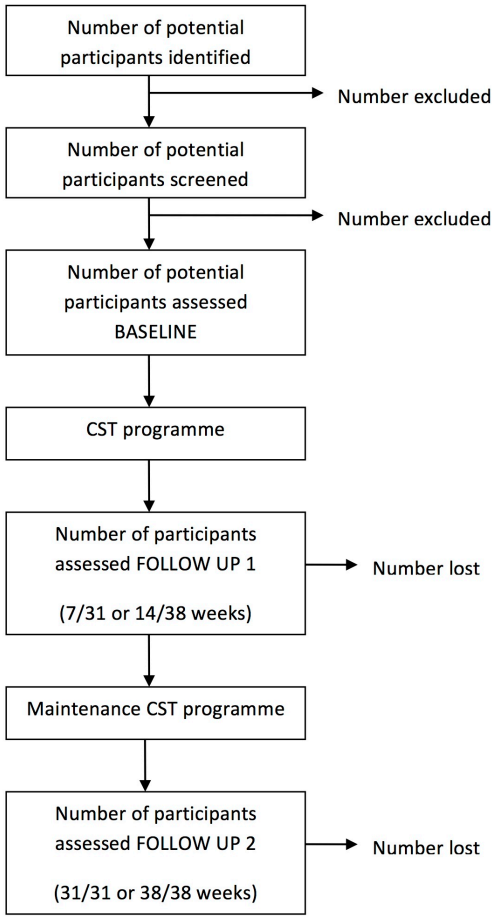
a) Meet the DSM–IV criteria for dementia [3]
b) Score between 0.5 and 2 on the Clinical Dementia Rating (CDR) [4]
c) Are able to see and hear well enough to participate in the group
d) Do not have major physical illness or disability which could affect participation
e) Do not have a diagnosis of a learning disability.

f) Able to communicate in English

Blinding

Researchers will not need to be blinded due to no randomisation taking place.

Flowchart of participants



Hypothesis for primary outcomes

Null hypothesis for the primary outcome: There is no difference between baseline and follow up 2, for maintaining the effects of CST at 31 or 38 weeks, for people with dementia.

Alternate hypothesis for the primary outcome: There is a difference between baseline and follow up 2, for maintaining the effects of CST at 31 or 38 weeks, for people with dementia.

The primary outcomes for the hypothesis testing will be cognition using the MMSE and quality of life using the QoL-AD.

Cognition – Mini Mental State Examination (MMSE) [5]
The primary outcome is cognition as measured by the Mini Mental State Examination (MMSE). The MMSE contains 10 categories comprising of orientation, registration, attention and calculation, recall, naming, repetition, 3-stage command, reacting, writing and copying. The MMSE has a score of up to 30 points and is widely used as a brief indicator of level of cognitive impairment. It has good reliability and validity.

Quality of Life- Alzheimer's disease Scale (QoL-AD)[6]
The QOL-AD covers 13 domains of quality of life. It has good internal consistency, validity and reliability and its use is recommended by the European consensus on outcome measures for psychosocial interventions in dementia [7].

Sample size calculation

The reality orientation (RO) review found a moderate effect size of 0.58 between the RO and control groups though the studies had some differences in methodology, outcome measures, and length of treatment/follow up. The MCST pilot study found a large effect size of 1.0 compared with CST alone. To detect an effect size of 0.32 with a power of 85% using a 5% significance with an estimated attrition rate of 15% a sample size of 100 is required.

Data management

The data will undergo a process of double checking upon entry into MACRO. A further audit will be conducted before final data extraction.

Analysis for primary outcomes

Demographics and baseline characteristics will be given for the whole sample, as well as being broken down by centre. Analysis will take place using SPSS version 18. Intention to Treat analysis will be used.

Missing data

There will be two types of missing data within this dataset. Missing items within measure and missing measures at time points.

For items missing within measure the rules for completing missing data for the relevant measure will be applied, see Table 1 Appendix 1. The missing data rules implemented for each measure are considered part of the validated tool and therefore will be used as designed in line with the original validation.

All summary scores for the measures will be calculated in line with the scoring rules established at the point of the measures validation. Deviance from these rules will be not undertaken in the main analysis of the trial.

Pro-rating for those measures with 20% missing will be carried out within participant. Once this has been applied there will only be missing time point data left.

We will apply a linear regression within treatment group to impute the summary scores for post randomisation time points in line with the trend seen within the group. That is, the group line of regression will be applied to the existing values for the participant. A sensitivity analysis will be conducted on all data with values imputed. Imputation for baseline measurements will be made solely within the baseline data set with no reference to randomised treatment group [8].

Clinical effectiveness methods

Primary model

The dependent variable in the model will be the score at 24 weeks (from the end of CST) on the two primary outcome measures.

Model 1. A paired t-test to test if there is a difference between baseline and follow up 1

Model 2. A paired t-test to test if there is a difference between baseline and follow up 2

Model 3. Models 1 and 2 will be repeated using repeated measures ANCOVA to take into account various covariates. Covariates considered will be whether the participant is taking cholinesterase inhibitors, age, gender, centre type, mode of delivery (7/14 week) and baseline score on the outcome measure, centre type

In total this will give at least 4 models in total for analysis.

Analysis for secondary outcomes

This section describes further analyses that will be done on the data.

Secondary models

A comparison to the MCST data will be conducted using independent sample t-tests. In total there were 11 centres; Of these 10 ran groups, 2 centres ran 2 groups giving a total of 12 groups. Six of these groups ran once a week, the remaining six ran twice a week. This structure will enable us to begin looking at the effect if once versus twice weekly and staff versus researcher led.

Additional outcomes

The adverse events, withdrawal rates and deaths will be tabulated across the trial.

List of tables

Baseline analysis

1. Demographic information of complete sample
    a. Type of centre (Frequencies)
    b. Specialist dementia setting (Frequencies)
    c. Gender (Frequencies)
    d. Age of PwD (Min, max, Mean, Standard Deviation)
    e. Ethnicity (Frequencies)
    f. Type of dementia (Frequencies)
    g. Use of AChEIs (Frequencies)
2. Demographics as above broken down by centre (geographic location)
3. MMSE score (Min, max, Mean, Standard Deviation)
4. Qol-AD (Min, max, Mean, Standard Deviation)

Interim analysis

Full analysis

List of figures

References

1. ICH E9 Expert Working Group. Statistical Principles for Clinical Trials: ICH Harmonized Tripartite Guideline. Statistics in Medicine 1999; 18:1905–1942.
2. CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. Schulz KF, Altman DG, Moher D for the CONSORT group. Ann Int Med 2010; 152 Epub 24 March 2010.

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SHIELD
Support at Home:
Interventions to Enhance
Life in Dementia

FORM 1: ADVERSE EVENTS IN RESEARCH INCIDENT REPORT FORM

ISRCTN No:	Full title of Study:	Principal Investigator:
28793457	MCST implementation in practice	Prof. Martin Orrell

SHIELD A/E No:	CRF	Description of Event	Start date	Duration/End date

Assessment			
Intensity:	☐ Mild ☐ Moderate ☐ Severe	Expectedness	☐ Expected ☐ Unexpected i.e. Not described in protocol,
Causality: Relationship to study intervention	☐ Not related ☐ Unlikely to be related ☐ Possibly related ☐ Probably related ☐ Definitely related	Seriousness	☐ Not serious ☐ Results in death* ☐ Life threatening* ☐ Results in hospitalisation or prolongation of existing hospitalisation* ☐ Results in disability or incapacity* ☐ Results in increased psychological distress* ☐ Other (please specify)*

Outcome	**Sequelae
☐ Resolved ☐ Ongoing ☐ Ongoing with sequelae**	

*** Possible Serious Adverse Event - report to SHIELD Principal Investigator/Programme Coordinator immediately. Ensure GP/CMHT Keyworker is aware.**

Reported by: Name: _____ Signature: _____ Date: _____

Appendix 7: Presentation and Publications

Appendix 7.1: Conference presentations

I have presented at a number of local, national and international conferences:

'Current research - SHIELD Maintenance CST study' at a CST training day, 2nd June 2010, Kent and Medway NHS Trust, UK.

'An Evaluation and Comparison of the Effectiveness of Two Different CST Approaches and their Implementation in Practice' at the Research and Development Open day, 24th June 2010, North East London NHS Foundation Trust, UK.

'Evaluation and comparison of the effectiveness of two different CST approaches and their implementation in practice', at the 27th International Conference of Alzheimer's Disease International, 26th March 2011, Toronto, Canada.

'Tools & skills to facilitate cognitive stimulation therapy groups effectively', at the 27th International Conference of Alzheimer's Disease International, 28th March 2011, Toronto, Canada.

'Cognitive Stimulation Therapy, maintenance CST and future research' at Memory Assessment and Therapy Service away day, 16th May 2011, Newmarket, UK.

'MCST implementation in practice', at the 10/66 meeting on CST, 18th October 2011, Havana, Cuba.

'Evaluation and comparison of the effectiveness of two different CST approaches and their implementation in practice', at the V Ibero American Conference on Alzheimer Disease, 21st October 2011, Havana, Cuba.

‘Cognitive Stimulation Therapy – Implementation into Practice’, at the 24th Annual St Louis University Summer Geriatric Institute, 12th June 2012, St Louis, America.

‘How research can deliver innovation - Cognitive Stimulation Therapy: A Redbridge Perspective’ at the Health and Wellbeing day, 6th October 2014, Barking, UK

Appendix 7.2: Development of maintenance CST

Removed due to copyright issues

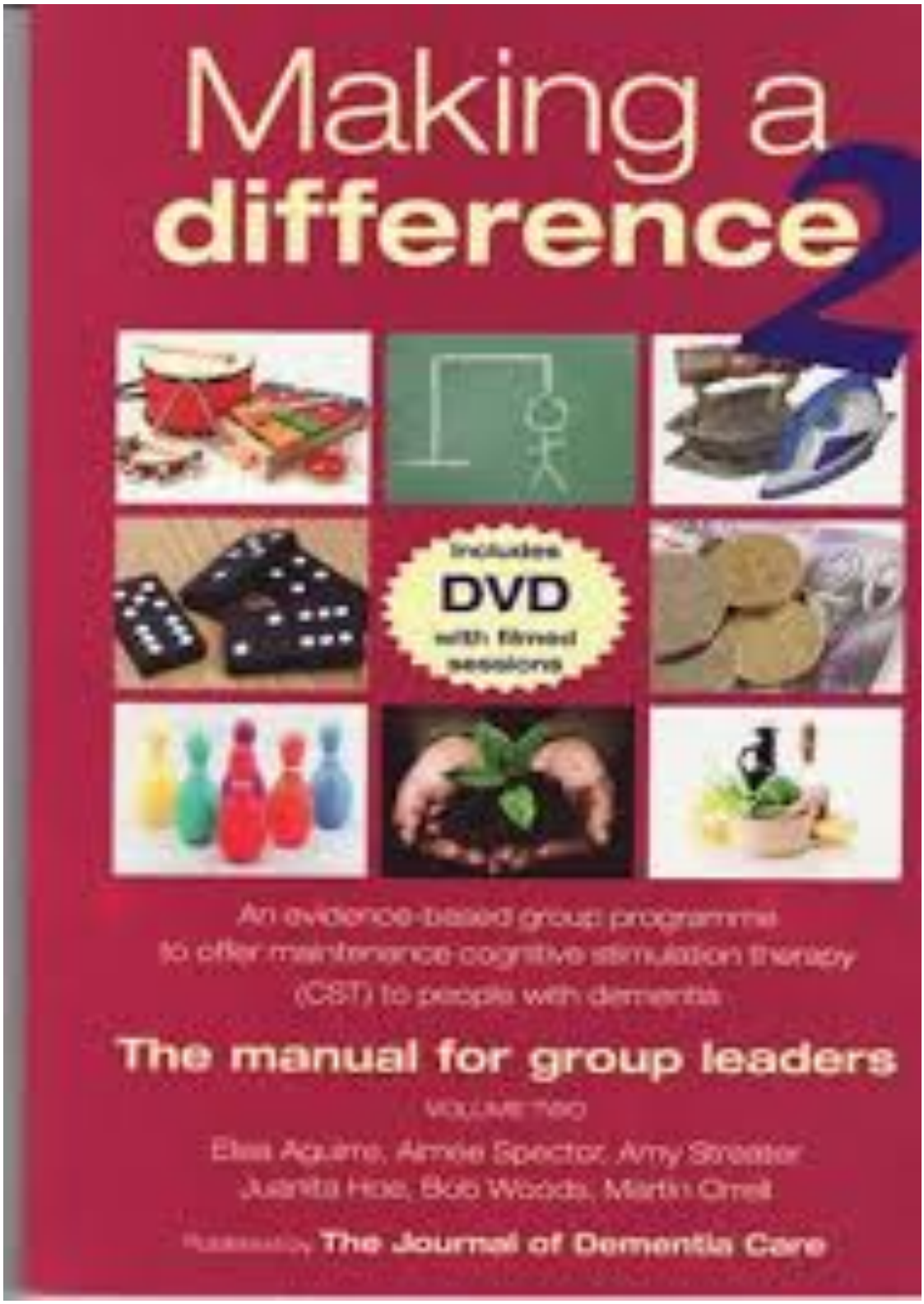
Appendix 7.3: Service users' involvement in the development of a maintenance CST programme

Removed due to copyright issues

Appendix 7.4: CST for people with dementia- who benefits most?

Removed due to copyright issues

Appendix 7.5: Making a Difference 2 manual



Appendix 7.6 Economic evaluation of maintenance CST

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Appendix 7.7: Results of a RCT of maintenance CST trial

Removed due to copyright issues

Appendix 7.8: Study protocol of maintenance CST trial implementation in practice

Streater *et al. Trials* 2012, **13**:91
http://www.trialsjournal.com/content/13/1/91

TRIALS

STUDY PROTOCOL Open Access

Maintenance Cognitive Stimulation Therapy (CST) in practice: study protocol for a randomized controlled trial

Amy Streater[1,6*], Aimee Spector[2,6], Elisa Aguirre[1,6], Juanita Hoe[1,6], Zoe Hoare[3], Robert Woods[4], Ian Russell and Martin Orrell[1,6]

Abstract

Background: Cognitive Stimulation Therapy (CST) is a psychosocial evidence-based group intervention for people with dementia recommended by the UK NICE guidelines. In clinical trials, CST has been shown to improve cognition and quality of life, but little is known about the best way of ensuring implementation of CST in practice settings. A recent pilot study found that a third of people who attend CST training go on to run CST in practice, but staff identified a lack of support as a key reason for the lack of implementation.

Methods/design: There are three projects in this study: The first is a pragmatic multi-centre, randomised controlled trial (RCT) of staff training, comparing CST training and outreach support with CST training only; the second, the monitoring and outreach trial, is a phase IV trial that evaluates implementation of CST in practice by staff members who have previously had the CST manual or attended training. Centres will be randomised to receive outreach support. The primary outcome measure for both of these trials is the number of CST sessions run for people with dementia. Secondary outcomes include the number of attenders at sessions, job satisfaction, dementia knowledge and attitudes, competency, barriers to change, approach to learning and a controllability of beliefs and the level of adherence. Focus groups will assess staff members' perceptions of running CST groups and receiving outreach support. The third study involves monitoring centres running groups in their usual practice and looking at basic outcomes of cognition and quality of life for the person with dementia.

Discussion: These studies assess the effects of outreach support on putting CST into practice and running groups effectively in a variety of care settings with people with dementia; evaluate the effectiveness of CST in standard clinical practice; and identify key factors promoting or impeding the successful running of groups.

Trial registration: Clinical trial ISRCTN28793457.

Keywords: Cognitive stimulation, Dementia, Staff, Training

Background

The worldwide population is rapidly aging [1], resulting in increased numbers of people with dementia [2]. The increase in demand for dementia-related services has long been anticipated. However, the planning and provision of services for people with dementia appear to be failing to meet increasing requirements [3]. Two thirds of people living in care homes have dementia, which in turn leads to an increasing level of dependency that can be attributed to a lack of stimulation, increased behavioural problems and the use of anti-psychotic medication [4]. There is a need to provide services in the community but also to improve the availability of psychosocial interventions.

CST is an evidence-based group programme for people with mild to moderate dementia [5]. A review of reality orientation (RO) [6] helped to develop CST as a brief psychosocial group intervention, focussing on implicit information processing. The development of CST

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http://www.trialsjournal.com/content/13/1/91

has followed the Medical Research Council (MRC) guidelines for the development and evaluation of complex interventions [7]. Cognitive stimulation leads to benefits in cognition and quality of life in the person with dementia [8], is shown to be cost effective and compares favourably with cholinesterase inhibitors for Alzheimer's disease [5,9]. Currently cognitive stimulation is the only non-pharmacological intervention to improve cognition recommended in the NICE-SCIE Guidelines for Dementia [10], which recommend that all people with mild to moderate dementia should be 'given the opportunity to participate in a structured group cognitive stimulation programme'.

CST is a twice-weekly, 7-week programme of stimulating 45-min group activities for people with dementia. A pilot study [11] of CST with an additional 16 weeks of once-weekly maintenance CST (MCST) sessions found a continued improvement in cognitive function for the people with dementia receiving maintenance CST. A large-scale RCT of maintenance CST (24 weeks of once-weekly sessions) versus CST only [12] has recently been completed as part of the SHIELD (Support at Home Interventions to Enhance Life in Dementia) project. The programme includes 7 weeks of CST and a further 24 weeks of maintenance CST sessions.

In recent years there has been an increase in the provision of CST, with around a third of the community mental health teams in the UK reporting using it [13]. This has been facilitated by the publication of the CST 'Making a difference' manual and the maintenance CST manual 'Making a difference 2' with a CST staff-training DVD [14,15]. However, there has been little research on the long-term implementation and evaluation of CST in practice.

A recent study found that after attending a CST training course, one third of the staff went on to implement CST groups in practice [16]. All staff members felt skilled enough to run the groups; however, they identified the need for management support, regular supervision, supervision from a specialist, online forums and additional training as useful in starting and running groups. Previous research into CST has reached phase III of the MRC framework for complex interventions [7]. This research aims to study the long-term implementation of CST within two linked trials and conduct a phase IV trial that will evaluate the effects of training, and the effects of outreach support and the long-term effects of CST in practice, and will help to understand the barriers and facilitators related to implementing CST in practice.

Methods

Design

This study includes three projects. The training and outreach trial and the monitoring and outreach trial differ in how staff members are recruited and in their previous exposure to training in CST. The observational study focuses on the effects of CST on people with dementia in the practice context. The three projects together will provide evidence on the most effective way of facilitating the implementation, uptake and effectiveness of the approach in a clinical context (see Table 1).

Training and outreach trial (TROU)

The design is a pragmatic, multi-centre, single-blind, two treatment arm, randomised controlled trial. All participants receive the training package as treatment as usual (TAU) consisting of the 1-day CST training, training DVD, CST manual and maintenance CST manual. Participants in the intervention group also receive outreach support (local coordinator, email support and online forum). The sample is dementia care staff from specialist and non-specialist dementia care settings. The staff are cluster randomised according to place of work, before the training day, to receive outreach support or

Table 1 Project overview

Title	Training and outreach trial	Monitoring and outreach trial	Observational study
Aim	To assess the effectiveness of staff training and outreach support	To assess the implementation in practice of CST and outreach support	To assess the effectiveness of CST in practice
Participants	Dementia care staff No previous CST experience or training	Dementia care staff Previously received CST manual/training	People with dementia
Number	120	120	100
Resources	CST manual maintenance CST manual DVD	CST manual maintenance CST manual DVD	CST manual maintenance CST manual DVD
Training	Yes	Variable	Variable
Outreach	50%	50%	No
Assessment timeframe	Baseline, 6 and 12 months	Baseline, 6 and 12 months	Before and after CST (0, 7 or 0, 14 weeks) and maintenance CST (31 or 38 weeks)

Streater *et al. Trials* 2012, **13**:91
http://www.trialsjournal.com/content/13/1/91

not. Each staff member completes three questionnaires, the first before the training day and at 6 and 12 months thereafter (Figure 1).

Recruitment

Recruitment to the trial includes staff from care homes, day centres and NHS Trusts from various locations across the UK. The trial is advertised through the Journal of Dementia Care, and the National Care forum and referrals are made through the commercial CST training day. The research team is then able to assess their eligibility for participating in the research. Follow-ups will also be made with centres that have expressed a previous interest in CST or attending a CST training day.

Participants

Staff members are screened to ensure they meet the inclusion criteria: (1) adequate written and spoken English, (2) able to complete online assessments at three different time points, (3) have at least two other team members with whom to run groups, (4) agreement from their management to have 2 h set aside per week to run the CST groups and 1 h following on from this for the 24-week maintenance CST programme, and (5) are able to provide between five to eight people with mild to moderate dementia who are willing to participate and meet the inclusion criteria (described in the observational arm). A minimum of three staff members is recruited per centre for logistical reasons of being able to consistently run the groups. Up to 40 centres are needed to be able to recruit the 120 staff members required for the trial. Working on the premise of a 15% attrition rate, the sample size will provide sufficient numbers for the staff training outreach support/no outreach support to estimate effect size and the feasibility of the trial. The attrition rate is an estimation based on previous research conducted in CST [12].

Training package

The CST and maintenance CST manual along with the DVD are distributed to all staff members participating in the trial. The CST 'Making a difference' manual describes an evidence-based programme of group activities providing stimulation for people with mild to moderate dementia based on the principles of person-centred care. The maintenance CST manual, 'Making a difference 2', follows

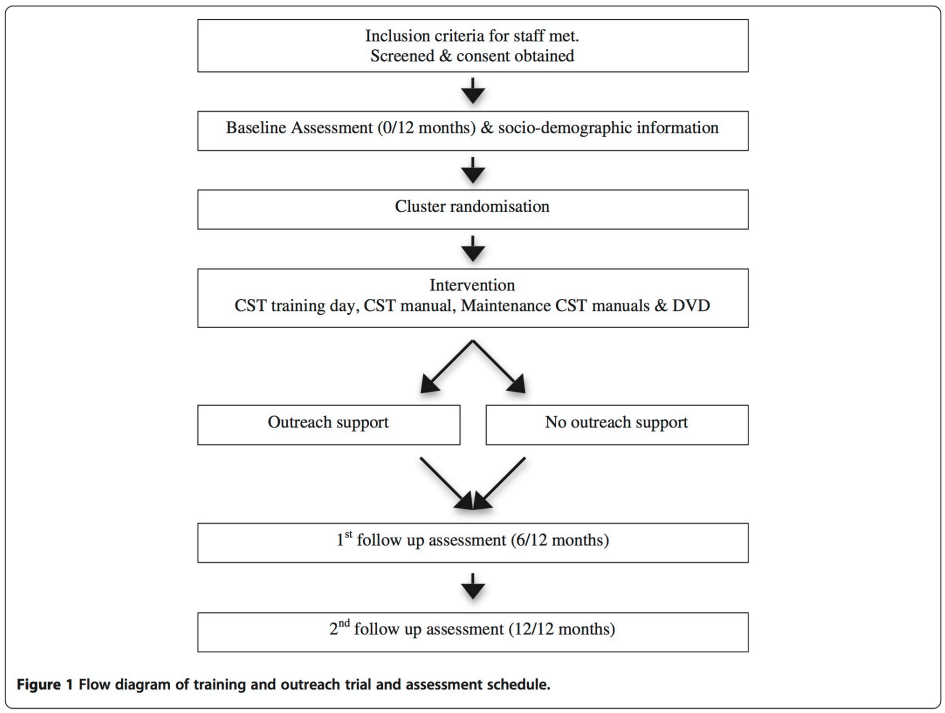

Figure 1 Flow diagram of training and outreach trial and assessment schedule.

on from the original programme and includes a 24-week structured programme of activities aimed at challenging yet empowering the person with dementia and comes with a staff-training DVD. The staff-training DVD comprises an introduction by Dr Aimee Spector as to what CST is, a table listing the order of the CST and maintenance CST sessions. and key principles. In addition to this, there is video footage of CST sessions with people with dementia for staff to observe and discuss. After each clip there are questions based on the key principles to encourage reflective learning and discussion. All staff members attend a CST training day. The training comprises the different perspectives of dementia, the main psychosocial approaches for dementia, the development and evaluation of CST, the session themes and examples of activities for sessions, key principles, planning of sessions and the setting up of a group, and reflective learning of issues that arise when implementing and running groups. The training uses learning methods such as role-play, small group exercise and use of the training DVD, and time is spent reflecting on the sessions and critically appraising how the session is run. Following on from the training day, it is advised that each session be run with two facilitators to enable them to jointly plan and reflect on the session, and complete the attendance and adherence forms together.

Randomisation

Cluster randomisation occurs prior to the staff attending the CST training day to ensure that staff members from the same centre receive the same level of support. The allocation ratio for randomisation is 1:1, into either the intervention or TAU. Randomisation is managed by email to the North Wales Organization for Randomized Trials in Health (NWORTH), which is an accredited trials unit, specialising in pragmatic trials.

Treatment as usual

Staff members within centres that are randomized to the control group deliver the CST as usual but without the additional outreach support. This can vary between centres and has the variability to change over time, but the training package offered to the intervention group will also be available to those in the control group. Therefore, the trial examines the additional effects of the outreach support.

Intervention

A pilot study conducted by our team identified that outreach support should consist of (1) an online forum, (2) email support and (3) local supervision [16]. The online forum is an online discussion site. It is accessible by user name and password. The first time a person attempts to enter the site, an email is sent to a member of the research team for approval in order to ensure they have been randomised to the intervention group. The use of a login allows us to record the number of people accessing the service, and how many times. Staff members are able to write up a variety of messages ranging from comments on sessions, to questions and advice. A researcher, who has extensive experience of CST and experience of running groups, delivers the email support (Amy Streater) and the service is made available as much as is needed by the staff members. A person familiar with CST and experience in running groups delivers the local supervision. The centre identifies the relevant person; however, if this is not possible a member of the research team provides the support. The role of the local supervisor is to help with the setting up of the CST group and also the practical issues that the staff members encounter when attempting to run CST groups. The supervisor records all the support given.

Primary outcome measure

The primary outcome measure is number of CST and maintenance CST sessions run in the centre by the follow-up at 31 weeks. This is recorded using the monitoring progress form located in the 'Making a difference' manual [14], which includes who was in attendance, level of interest, communication, enjoyment and mood, on a rating scale 1–5. This measure is being completed at the end of each session from baseline to 31 weeks (inclusive of maintenance CST), until the maintenance CST groups have been completed or until the groups have been discontinued.

Secondary outcome measures

a) The level of adherence to the CST and maintenance CST programme is measured by a adherence list designed as part of the research. It is based on the 18 key principles as developed as part of the maintenance CST programme [15]. The responses are reviewed by a researcher to mark whether staff are adhering to the key principles as laid out in the 'Making a difference 2' manual. Any ambiguity of responses given by the participants will be discussed with another researcher until a consensus is reached as to whether they are adhering to the key principles.
b) Job satisfaction [17] is measured using the Minnesota Satisfaction Questionnaire (MSQ). It is made up of 100 questions and comprises 20 dimensions with five items per scale with a 5-point Likert rating scale. The measure has adequate internal reliability.
c) Staff members' approach to dementia is measured using the Approaches to Dementia Questionnaire

(ADQ) [18]. The ADQ has 19 statements about the person with dementia and the care they receive. The scale has high validity and good reliability using Cronbach's α for its person-centeredness and hopefulness subscales [18].

d) Knowledge is measured using the Dementia Knowledge–20 (DK-20) [19]. There are 20 questions for which there are five possible answers. The scale has sufficient reliability and is administered at baseline and final follow-up only.
e) Perceived sense of competence is measured using the Sense of Competence in Dementia care–Staff questionnaire (SCIDS) [20]. It comprises 17 items categorised into four subscales: professionalism, building relationships, care challenges and sustaining personhood. The scale has good internal consistency.
f) Learning characteristics of staff are measured using the brief Learning Transfer System Inventory (LTSI) [16,21]. The constructs of the LTSI are validated using common factor analysis [22,23]. The brief form comprises of 16 questions that are categorized into four major groups: trainee characteristics, motivation, work environment and ability [22]. All the items use five-point Likert-type scales from 1, strongly disagree, to 5, strongly agree.
g) Barriers to change within the workplace are measured using the Barriers to Change Questionnaire (BARCQ) [24]. It comprises 19 questions focussing on: institutional constraints, support from colleagues, philosophical opposition, client dissatisfaction, interference and positive factors. It also allows the addition of any further comments.
h) The emotional and behavioural responses relating to challenging behaviour presented by the person with dementia are measured by the Controllability Beliefs Scale [25]. The scale has 15 items based on a 5-point scale. The height of the score establishes the belief of the staff member in relation to the level of control demonstrated by the person with dementia. The scale has good internal reliability.
i) Focus groups with staff and managers will be conducted in both the TROU and MONOU trial to obtain qualitative data with regards to people's perception of running groups and outreach support. They will run in a variety of care settings, and follow a semi-structured interview schedule, using inductive thematic analysis to code and analyse the gathered data.

Consent

Staff members give informed consent and it is made clear that they will be of no disadvantage if they choose not to participate further at any stage during the trial. Consent is also sought from a member of management in order to give staff the optimum chance of carrying out CST in their workplace. Ethical approval was granted June 2011 by East London REC 3.

Blinding

Although staff members cannot be blinded to their allocation, all assessment data are completed online and independently of the research team. Once the staff member has completed the survey, an administrator on the SHIELD programme team assigns all staff members a code for identification purposes to maintain anonymity throughout the trial. The researcher administering the outreach support has the contact details of the staff members but is unaware of their individual code; hence they are blind in identifying the staff members. However, it is common for participants to inadvertently inform researchers of the strand of the trial they have been allocated to. To reduce the risk of this, once staff members are aware of their code it is emphasised that it is not to be discussed with any members of the research team. This reminder is included in the email sent by a member of the research team to complete the follow-up assessments.

Monitoring and outreach trial (MONOU)

The design is a pragmatic, multi-centre, single-blind phase IV trial. Participants are staff members from centres that have previously purchased the CST 'Making a difference' manual or attended a CST training course. The staff members are currently in possession of the CST manual or attended CST training. In addition to this, they all receive the maintenance CST manual and DVD. It is recorded whether participants have the manual only or manual and training. Centres are cluster randomised into outreach support or no outreach support (Figure 2). The time points for completing the questionnaire are the same as the training and outreach trial. However, they also complete a retrospective questionnaire on their use of CST in practice prior to the research.

Recruitment

Recruitment of staff members who have purchased the manual is based on referrals by Hawker publications. A database of attendees generated from previously run CST training days allows us to approach people who have attended CST training. Staff members are then contacted to determine if they are interested in participating in the study. A CST poster advertises the research on the CST website (www.cstdementia.com), SHIELD (www.ucl.ac.uk/shield), and through the Journal of Dementia Care. The project is also a UKCRN portfolio-adopted study allowing NHS Trusts nationwide to be

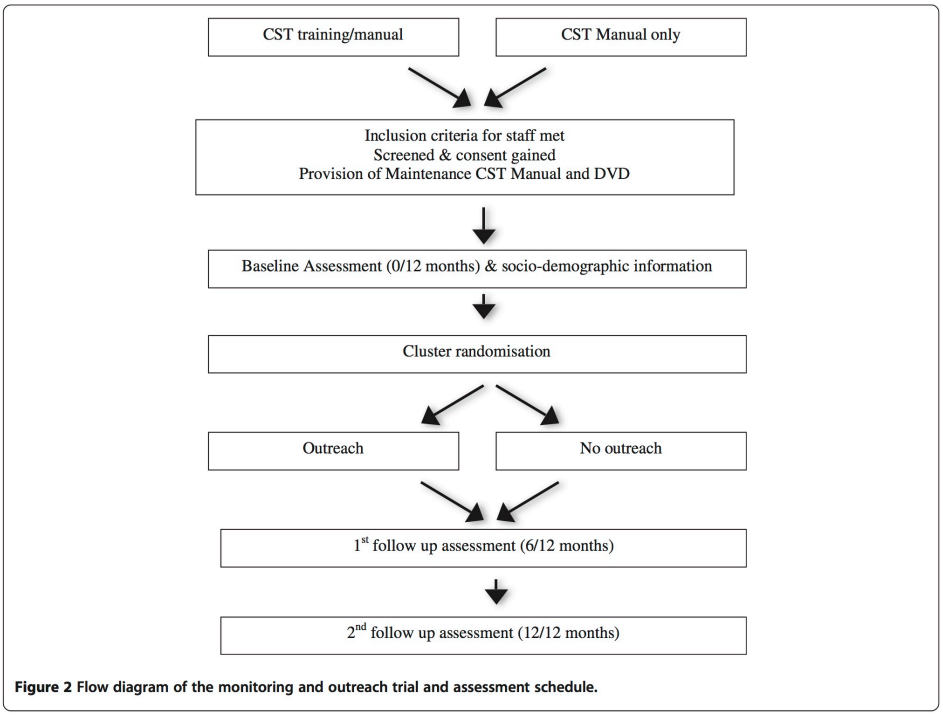

Figure 2 Flow diagram of the monitoring and outreach trial and assessment schedule.

able to approach the research team in order to assess their eligibility for participating in the research.

Participants

Participants are dementia care staff who have the CST manual or attended the CST training day, and are able to implement the CST programme once or twice weekly. The screening and inclusion criteria match those for the training and outreach study but a minimum of one staff member can be recruited per centre.

Randomisation

Randomisation is identical to the TROU trial. Before randomisation it is recorded who has the manual or manual and training. At various time points during the recruitment of the participants the centres are divided into two clusters, taking into considerations the size of the centre and type of previous training (manual vs. manual and training). This matched pair of clusters is then independently cluster randomized to receive the intervention or TAU by remote email service to N-WORTH. Because of differing numbers per centre we will endeavour to keep similar numbers in the control and experimental group, with an allocation ratio for randomisation of 1:1, into either the intervention or TAU group.

Treatment as usual

Sites that are randomised to the control group deliver the CST as usual. This can vary between centres and has the variability to change over time. The trial examines the additional effects of the outreach support and long-term effect in practice.

Intervention

The outreach support options are identical to those in the training and monitoring study, with one difference: to emulate CST in practice, staff members identify the local supervisor, and if this is not possible, it is recorded accordingly. All the staff members randomised to receive outreach support are encouraged to use all the options available to them, but they are not compulsory. The staff

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member is monitored to measure their usage of the outreach support options.

Primary outcome measure

The primary outcome is identical to the TROU trial. However, due to the nature of the recruitment, in that people are being recruited who have previously purchased the 'Making a difference' manual or attended CST training, it will be dependent on people's interest in taking part in the research. As a minimum of one staff member can participate per centre; between 40 and 120 centres are required to recruit 120 staff members. This figure also accounts for a 15% attrition rate.

Secondary outcome measures

The secondary outcome measures are identical to those in the TROU trial.

Consent

Informed consent is gained from each staff member and a member of management, and is identical to the training and outreach trial. Ethical approval was granted June 2011 by East London REC 3.

Blinding

The procedure for blinding is identical to the TROU trial.

Analyses

Training and outreach trial & Monitoring and outreach trial

A combined analysis making use of the results from the training and outreach trial (120 participants) and the monitoring and outreach trial (120 participants) will be carried out. The primary outcome will be the mean number of CST sessions offered per centre assuming the intra-cluster correlation p to be 0.05. At the 6-month primary end point based on 240 staff members (120 outreach vs. 120 control) in the outreach group, the mean number of sessions offered is estimated to be 16 (SD 10) and in the control group the mean number of sessions offered is expected to be 12 (SD 10). Setting p at 0.05, power at 0.8, with the effect size at 0.4, then 200 participants would be required to demonstrate a difference between the groups.

Using all the participants recruited across both trials (TROU and MONO), a four-group comparison will also be made. This will compare training and outreach support, training and no outreach support, manual only and outreach, and manual only and no outreach support. This will determine if there are differences between these groups at 6 and 12 months.

Observational study of CST in practice

The design is a multi-centre, longitudinal observational study with people with dementia. Sites that are currently running or in the process of setting up CST groups complete minimal outcome measures at three time points with people with dementia who are participating in the CST and maintenance CST programme (Figure 3). The measures are being completed before the group starts (baseline), 7 or 14 weeks depending on how they implement the CST programme (once or twice weekly), and after the maintenance CST at 31 or 38 weeks. The intervention is CST as routinely offered in the care setting. The aim of this study is to determine whether groups are running in practice and demonstrate the positive findings for cognition and quality of life of life for the person with dementia found in previous CST research [5,11].

Recruitment

Centres that are running CST groups are approached, and the staff asked to complete measures in cognition and quality of life with the people with dementia taking part in the groups. The centre type, level of staff experience and training are recorded. The centres are given the maintenance CST manual and staff training DVD. Recruited participants have a confirmed diagnosis of mild to moderate dementia.

Participants

Centres that are currently running or setting up CST groups are approached to participate in the observational study. Approximately 13 centres are needed to provide us with 100 people with dementia and experienced staff in dementia care. The person with dementia will have (1) a score of between 0.5 and 2 on the Clinical Dementia Rating scale [26] and (2) a diagnosis of dementia, (3) adequate spoken and written English, (4) the ability to participate in a 'meaningful' conversation and (5) remain in a group for 45 min. Participants also need (6) adequate eyesight and hearing, (7) to be able and willing to give informed consent, and (8) able to complete a cognition and quality of life measure at three intervals over a year. If five to eight people with dementia give informed consent to complete the minimal outcome measures, with a staff member or researcher, the centre is recruited in to the study and a letter explaining their participation in the research is sent to their GP.

Training package

The staff members within the centres have the CST manual or previously attended CST training, which includes the CST manual. In addition the centre will receive the Maintenance CST manual and DVD.

Randomisation

This is a naturalistic study of CST in practice so people with dementia who are about to start CST groups are

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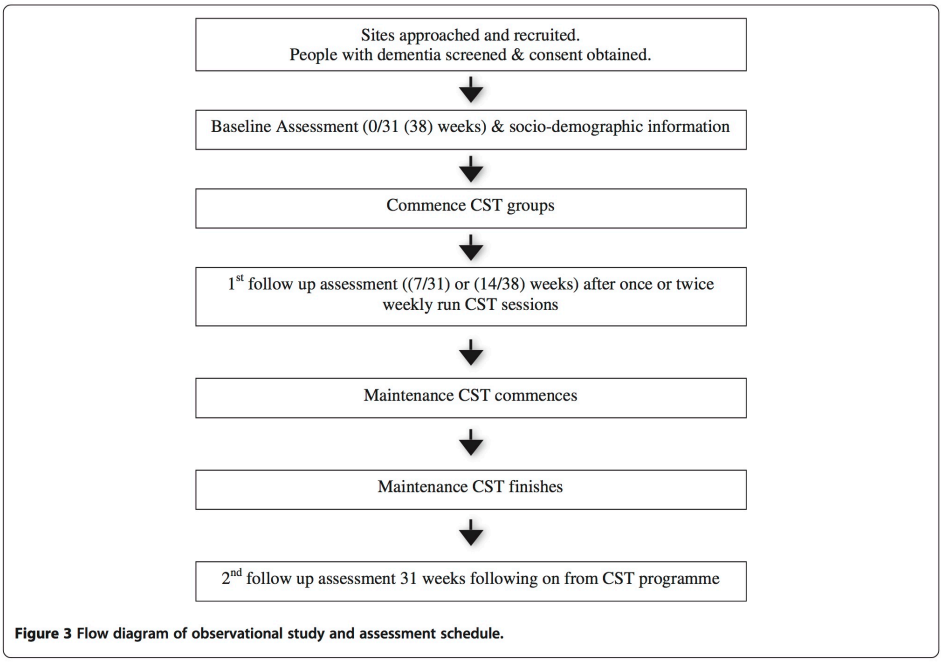

Figure 3 Flow diagram of observational study and assessment schedule.

approached and informed, and consent obtained. They are then assessed at three time points (0, 7 and 31 weeks or 0, 14 and 38 weeks) throughout their participation in the trial.

Outcome measures

The primary and secondary outcome measures for people with dementia are completed at baseline (T0) prior to the CST programme starting, then post CST groups (T1) (at 7 or 14 weeks depending on whether groups are implemented once or twice weekly). The final follow-up will be completed 24 weeks after the maintenance CST has commenced (T2). Socio-demographic information is collected about the person with dementia including age, gender, race, diagnosis of dementia, type of diagnosis and medication. Medication will be recorded at each follow-up to mark any differences for the duration of their participation in the trial.

a) The primary outcome is cognition as measured by the Mini Mental State Examination (MMSE) [27]. The MMSE has a score of up to 30 points and is widely used as a brief indicator of level of cognitive impairment. It has good reliability and validity.

b) The secondary outcome measure is quality of life as measured by the Quality of Life-Alzheimer's Disease (QoL-AD) [28]. The QoL-AD is a 13-item scale measuring different aspects of life. The scale totals 52 points and higher scores indicate better quality of life. It has good internal consistency, validity and reliability [28,29].

Consent

It is expected that the participants are competent to provide informed consent to participate in the trial. The British Psychological Society guidance on evaluation of capacity will be adhered to. In addition, consent is an on-going process as opposed to a one-off decision and this will be continually monitored throughout the study. Mental Capacity Act [30] guidance will also be applied where relevant, such as when then a participant is no longer able to give informed consent. A person's preference can be indicated by their initial willingness to participate in the trial. However, if any distress or discomfort is evident during the study the person will be withdrawn. Ethical approval was granted on June 2011 by East London REC 3.

Blinding

Blinding is unnecessary for the staff members and researchers, as each person with dementia has the opportunity to participate in the CST and maintenance CST programme and the staff members are completing the assessment at each time point.

Analyses

Analysis will be a pre-post analysis based on intention to treat, in that all collected data made available by the person with dementia will be included, regardless of whether they complete the programme or not. Imputation methods such as the last observation carried forward are of limited use in dementia, as there is the expectation of a gradual decline and for participants to be lost through illness or death. A linear regression model will be used where data are missing in order to predict the missing value and impute the total when possible. The sample size calculation accounts for the number of people expected to be available at the study end point. All participants are in receipt of the CST and maintenance CST programme. Analysis will take into account the evaluation at 24 weeks after CST as the primary end point. Secondary analysis will consider the effects immediately following the CST programme. Age, gender, cholinesterase inhibitor and baseline scores on the two scales being measured will be entered as covariates, together with 'centre' entered as a random factor.

Ethical arrangements

Risks and anticipated benefits for trial participants

There appear to be no documented harmful side effects from participating in either CST training or in the running of the CST and maintenance CST programme, and no adverse reactions are apparent. People with dementia who have participated in previous CST groups consistently report benefits of feelings of validation, self-worth and overall enjoyment of the sessions [31]. Potential participants, both staff members and people with dementia, will be fully informed of the potential risks and benefits of the project. A reporting procedure is in place to ensure that serious adverse events (SAEs) are reported to the Chief Investigator. SAEs that are considered to be related and unexpected are reported to the Multicentre Research Ethics Committee and the trial Data Monitoring and Ethics Committee.

Discussion

This project will pragmatically evaluate the effectiveness of staff training and outreach support by increasing the delivery of CST in practice by outreach support intervention both in new CST practitioners (TROU trial) and experienced CST practitioners (MONOU trial). The NICE-SCIE guidelines recommend CST, and this project aims to record the uptake and delivery of CST in dementia settings, to determine if it is easy to follow and replicable in practice. The MONOU trial provides a naturalistic evaluation of benefits of manual only versus manual and training in CST implementation, and both the TROU and MONOU trial will identify staff and situational factors that impede or facilitate CST implementation. One of the important advances in this study is to measure the adherence by specific questions developed in direct relation to the key principles that define CST as a therapy. It also allows the research to demonstrate, on a large scale, the knowledge, views and understanding, and approach of staff members to dementia in a variety of care settings nationwide with the secondary outcome measures. In relation to the observational study it provides an evaluation of the long-term cognitive and quality-of-life benefits of CST and maintenance CST in practice.

This study should provide definitive evidence of the effectiveness and feasibility of implementation of CST and maintenance CST in a variety of care settings. This study is likely to influence the availability, provisions and uptake of CST and maintenance CST in the UK and internationally, and may also impact on current evidence-based guidelines and policies relating to dementia care.

Trial status

Ongoing

Abbreviations

CST: cognitive stimulation therapy; UK: United Kingdom; TROU: training and outreach; MONOU: monitoring and outreach.

Competing interests

AS, RTW and MO have co-authored a CST manual, and AS, RTW, MO, JH, EA and ASt co-authored the maintenance CST manual, the royalties from which are received by the Dementia Services Development Centre Wales. AS also runs the CST training course on a private basis.

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Authors' contributions

MO developed the original concept of the trial, and AS, JH, ASt, EA, ITR and ZH developed the design and methodology; all authors reviewed and commented on drafts of the protocol and paper. All authors read and approved the final manuscript.

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